Guidance Document for the Notification and Testing of New Chemicals and Polymers

Draft: March 2021

Pursuant to section 69 of the *Canadian Environmental Protection Act, 1999*

Government of Canada
Environment and Climate Change Canada
Health Canada

Contact Information for the New Substances Program

Comments and Inquiries

Comments regarding the *New Substances Notification Regulations (Chemicals and Polymers)* as well as technical questions or requests for additional information about procedures for New Substances Notifications or on the status of submitted New Substances Notifications should be directed to:

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Individuals may also visit the New Substances program website at https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html.

or the *Canadian Environmental Protection Act, 1999* Registry at https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry.html.

New Substances Notification Form and the Guidance Document

The New Substances Notification Form may be obtained electronically from the New Substances program website indicated above or by contacting the Substances Management Information Line. The New Substances Notification Form may be reproduced without permission.

Cette publication est aussi disponible en français. Vous pouvez en obtenir une copie électronique en visitant le site internet des Substances Nouvelles mentionné ci-haut.

Although care has been taken to ensure that this Guidance Document accurately reflects requirements prescribed in the *Canadian Environmental Protection Act, 1999* (the Act) and the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations), notifiers are advised that should any inconsistencies be found, the Act and the Regulations will prevail.

Abstract

This document (referred to as the Guidance Document) has been prepared to assist notifiers responsible for complying with the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) of the *Canadian Environmental Protection Act, 1999* (the Act).

This Guidance Document is meant to help notifiers determine whether a substance subject to notification under the Regulations and identify the information requirements. In addition, it provides

- step-by-step instructions for the completion of a New Substances Notification (NSN);
- user-friendly flowcharts to aid in determining the appropriate schedule to file (see Appendix 1);
- technical considerations of the information requirements;
- detailed instructions on how to complete the New Substances Notification Form;
- identification of appropriate test procedures and practices to use; and
- an outline of how confidential information should be submitted.

This Guidance Document concludes with an explanation of how the New Substances program assesses the information submitted in a New Substances Notification and the implications of the assessment decisions for notifiers.

Note: Living organisms not listed on the Domestic Substances List may be subject to the *New Substances Notification Regulations (Organisms)* and are not addressed in this Guidance Document, which is specific to chemicals, biochemicals, polymers and biopolymers. To determine whether a living organism is subject to notification under the *New Substances Notification Regulations (Organisms)*, please refer to the *Guidance Document for the Notification and Testing of New Living Organisms*.

Résumé

Le présent document (appelé les Directives) a été rédigé pour aider les déclarants à se conformer au *Règlement sur les renseignements concernant les substances nouvelles (substances chimiques et polymères)* (le Règlement) de la *Loi canadienne sur la protection de l'environnement (1999)*.

Les Directives ont pour but d'aider les déclarants à établir si une substance doit être déclarée en vertu du Règlement et à déterminer quels renseignements fournir. Elles renferment également des instructions détaillées pour compléter une déclaration de substances nouvelles, des diagrammes permettant de décider facilement quelle annexe doit être produite (voir l'appendice 1), des précisions sur les renseignements techniques exigés, des renseignements détaillés sur la manière de remplir le formulaire de déclaration de substances nouvelles, l'énumération des pratiques et procédures d'essai appropriées et un aperçu de la méthode de communication des renseignements confidentiels.

Enfin, elles précisent comment le Programme des substances nouvelles évalue les renseignements fournis dans une déclaration de substances nouvelles et expliquent les implications des décisions d'évaluation pour les déclarants.

Remarque : Les organismes vivants ne figurant pas à la *Liste intérieure* peuvent être assujettis au *Règlement sur les renseignements concernant les substances nouvelles (organismes)*. Ils ne sont pas visés par ces directives qui concernent les substances chimiques et biochimiques ainsi que les polymères et les biopolymères. Pour déterminer si, en vertu du *Règlement sur les renseignements concernant les substances nouvelles (organismes)*, il faut déclarer un organisme vivant, veuillez consulter les *Directives pour la déclaration et les essais de substances nouvelles : organismes*.

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How to Use the Guidance Document

This Guidance Document has been prepared for the benefit of any person interested in the provisions of the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) made under the *Canadian Environmental Protection Act, 1999* (the Act). A review of the sections of this Guidance Document, listed below, will allow the reader to focus on requirements specific to his or her circumstances.

The key to avoiding unnecessary delays when preparing a New Substances Notification is to thoroughly understand the properties of a substance in question and how to apply the Regulations, which this Guidance Document will help you understand.

This Guidance Document is organized into 10 sections:

1. **Introduction and Overview** — explains the purpose, statutory powers and features of the New Substances program.

2. **The Inventories** — explains the Domestic Substances List and the Non-domestic Substances List, how these are amended and how to locate a substance specified on them.

3. **Substances** — helps to determine whether the substance to be manufactured, imported or used must be notified; provides definitions of special categories, substances not subject to notification and substances subject to notification.

4. **Notification Information Requirements** — if the substance is subject to notification, this section helps identify the appropriate Schedule to be provided and determine when the New Substances Notification must be provided to the Minister of the Environment via the New Substances program.

5. **New Substances Notifications** — provides instructions for completing the information required for a New Substances Notification.

6. **The New Substances Notification Form** — describes the process to complete the New Substances Notification Form and the meaning and intent of each information requirement; also elaborates when data elements are not required.

7. **Confidential Information** — describes issues pertaining to confidential business information, such as confidentiality claims, masking of substance identities and determining the presence of confidential substances listed on the Domestic Substances List and the Non-domestic Substances List.

8. **Recommended Test Protocols and Alternative Approaches** — provides guidance on acceptable test methods and “alternative” information and describes features of subsection 81(8) of the Act, which provides for the waiver of information requirements when one of several criteria is met. The New

Substances program provides the opportunity for notifiers to submit a Pre-notification Consultation request (see section 8.8) to resolve notification issues while the New Substances Notification is being prepared.

9. **Processing a New Substances Notification** — explains what happens after a New Substances Notification is received, including how the New Substances Notification is processed and reviewed and the types of correspondence that could be issued by the New Substances program.

10. **Post-notification Responsibilities** — reviews obligations of notifiers and the New Substances program after a New Substances Notification has been submitted.

Further clarification and updates on any topic covered by this Guidance Document can be obtained from the New Substances program website at https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html or by contacting the Substances Management Information Line by telephone at 800-567-1999 (within Canada) or 819-938-3232 (outside Canada) or by e-mail: eccc.substances.eccc@canada.ca.

SECTION 1 — INTRODUCTION AND OVERVIEW

1.1 Purpose of This Guidance Document

This Guidance Document provides assistance for complying with the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations). It explains the information that a person[1] manufacturing or importing a new substance into Canada (the notifier) must submit to the Minister of the Environment (the Minister) under subsections 81(1) and 81(4) of the *Canadian Environmental Protection Act, 1999* (the Act) before manufacturing or importing a chemical/biochemical[2] or polymer/biopolymer[3] that is not on the Domestic Substances List (DSL).[4] This information is required so that the Minister or the Minister of Health may determine whether the substance is toxic or capable of becoming toxic within the meaning of section 64 of the Act. When the term "toxic" is used in this Guidance Document, it refers to the interpretation in section 64 of the Act (see section 9.5.2). This Guidance Document also discusses the obligations of the Minister of the Environment and the Minister of Health (the Ministers) to respect assessment periods and those of the Minister to add a chemical or polymer to the DSL under section 87 of the Act.

Note that the *Guidance Document for the Notification and Testing of New Substances: Chemicals and Polymers* does not address the *New Substances Notification Regulations (Organisms)*. Information pertaining to the regulations for living organisms can be found in the *Guidance Document for the Notification and Testing of New Living Organisms*.

The New Substances (NS) program consists of officials from both Environment and Climate Change Canada and Health Canada. Each department conducts an assessment of the information provided to the Minister in the New Substances Notification (NSN).

1.2 The Canadian Environmental Protection Act, 1999

The Act is a statute about sustainable development and pollution prevention. These purposes are achieved or furthered through many mechanisms, among them the NSN regime, a regime requiring that the Ministers must assess substances that are not on the DSL in order to determine whether they should be subject to actions taken after the assessment. The assessment is based on the criteria set out in section 64 of the Act.

[1] The term “person” includes legal and natural persons such as corporations or individual residents of Canada.
[2] When the term “chemical(s)” is used in this Guidance Document, it refers to both chemicals and biochemicals.
[3] When the term “polymer(s)” is used in this Guidance Document, it refers to both polymers and biopolymers.
[4] The term “Domestic Substances List (DSL)” is used inclusively in this Guidance Document to specify substances listed either publicly or confidentially on the inventory.

1.3 Overview of the New Substances Provisions under the Act

Notification is required if a substance is subject to sections 80–89 of the Act. Substances that require notification are the following:

a) substances new to Canada (i.e., those not on the DSL) that are manufactured in Canada or imported into Canada; and
b) substances used to undertake a Significant New Activity (SNAc) (see section 9.6).

The Act features a number of provisions, including criteria for identifying substances requiring notification; notification obligations for manufacturers and importers; a detailed assessment mechanism; and enabling authorities to take action after the assessment.

In the Act, the approach to the management of new substances is both proactive and preventive, employing a pre-manufacture or pre-import notification and assessment process. When this process identifies a new substance that may pose a risk to human health or the environment, the Act empowers the Minister to intervene prior to or during the earliest stages of its introduction to Canada. This ability to act early makes the NS program a unique and essential component of the federal approach to the sound management of chemicals in Canada.

The Regulations specify the information that must be provided to meet the notification obligations. The main regulatory features of the NS program are

- establishment of categories of substances;
- identification of administrative and other information requirements;
- specification of conditions, test procedures and laboratory practices to be followed when developing test data;
- timing of notification before manufacture or import or beginning of a SNAc; and
- requirements for the NS program to assess information within a set time.

To meet the need for evaluating different categories of substances, information requirements are determined by separating substances into categories and notification groups. Substances are first generically categorized by substance type (e.g., chemicals and polymers), and then each substance type is further separated into notification groups based on factors such as quantity of manufacture or import or proposed use (e.g., research and development). This system of notification groups allows the NS program to match information requirements with anticipated concerns about quantities and characteristics of specific groups of substances.

The assessment process begins when the NS program receives an NSN for a new substance proposed to be manufactured or imported. NSNs must contain all required administrative and technical information prescribed in the Regulations, including the appropriate fee (if applicable), and substantiation of confidentiality claims. NSNs must be provided to the NS program 5 to 75 calendar days prior to exceeding the applicable trigger quantity according to the notified Schedule.

Significant New Activity Notifications (SNANs) must contain all prescribed information specified in the SNAc Notice or SNAc Order (see section 9.6.2) and must be provided prior to undertaking a SNAc according to the timelimes prescribed in the SNAc Notice or SNAc Order (typically 90 days prior to the commencement of the SNAc).[5]

Sometimes a quantity is specified in the SNAc Notice or SNAc Order (e.g., any activity involving more than 10 kilograms per calendar year). In these cases, any person proposing a SNAc for the substance shall provide the prescribed information at least 90 days **before** exceeding 10 kilograms per calendar year.

When a quantity is not specified in the SNAc Notice or SNAc Order, any person proposing a SNAc for the substance (0 kilograms per calendar year) shall provide the prescribed information required in the SNAc Notice or SNAc Order 90 days prior to the commencement of the proposed SNAc .

Environmental and human health risk assessments are conducted on the information provided and any other information that is available to the NS program to determine whether the substance is toxic or capable of becoming toxic (see section 9.5.2). These assessments are required to be completed within the prescribed assessment period and may result in any of the following by the NS Program on behalf of the Minister:

a) a determination that the substance is not toxic or capable of becoming toxic;
b) a determination that the substance is toxic or capable of becoming toxic, which may require
    i) the establishment of conditions to restrict the manner in which the notifier may manufacture or import of the substance;
    ii) prohibition of manufacture or import of the substance; or
    iii) prohibition of manufacture or import of the substance to the person to whom the request is directed pending submission and assessment of additional information determined to be required for the purpose of the assessment; or
c) a suspicion that a SNAc in relation to the substance may result in the substance becoming toxic. In such instances, a SNAc Notice will be issued for the substance.

1.4 Who Is Required to Notify?

Under the Regulations and section 81 of the Act, any person (individual or corporation) manufacturing a new substance in or importing a new substance into Canada (notifier) must provide the NS program with an NSN. This NSN must contain all information specified in the Regulations.

The notifier is responsible for complying with the Regulations and must submit the appropriate NSN corresponding to the quantities of the substance being manufactured or imported. The notifier is required to provide the information in the NSN Form (see section 6).

[5] Additional SNAc Guidance can be found online at https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/significant-new-activity-provisions.html.

By signing the certification statement (block A.1.1) on the NSN Form, the notifier accepts all other compliance responsibilities, including filing any subsequent schedules that may be required and providing the appropriate fee, and will be required to keep the information and any supporting data for a period of five years, as per section 13 of the Regulations.

1.4.1 Transfer of Notification Status – Certification Form – Interpretation of Person

Subsection 81(5) of the Act provides a rule of succession in the case of the transfer of certain rights in respect to substances subject to section 81 of the Act.

Successors to which subsection 81(5) applies are requested to sign a Certification Form prior to change of ownership if they wish to take advantage of the current notification status of a substance. This includes companies that are undergoing a company name change. This form indicates the transfer of rights or privileges, in relation to information provided for the substance, from the original notifier to the successor.

This form can be obtained from the NS program website at https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notification-forms.html or by contacting the Substances Management Information Line.

The Certification Form must be signed by an officer of the successor and include all NSNs to which the change of ownership applies.

This provision allows successors to continue manufacturing or importing a new substance without having to submit a new notification.

1.4.2 Canadian Agent – Subsection 14(3) of the Regulations

If the notifier providing the NSN is not a Canadian resident, he or she must identify, under paragraph 14(1)(*b*) of the Regulations, a Canadian resident who is authorized to act on his or her behalf as the “Canadian Agent.” All notices and correspondence from the NS program will be sent to the “Canadian Agent,” who will be required to keep the information and any supporting data for a period of five years after the end of the year in which the information is provided as per section 13 of the Regulations.

As an example, a notifier who is not a Canadian resident but, for the substance being imported, possesses “Canadian Importer Status” and is listed as the “Importer of Record” on the Canadian Customs coding form (Form B3-3) as issued by the Canada Border Services Agency must identify a person residing in Canada who is authorized to act on the notifier’s behalf as the “Canadian Agent.”

The “Canadian Agent” is responsible for ensuring that information in the NSN is accurate and complete**.**

Please note that the “Canadian Agent” cannot be the importer of the new substance. If the “Canadian Agent” is importing the substance directly and reselling, repackaging, distributing, etc. from his or her location in Canada, then he or she is the importer of record and an NSN must be completed identifying the person as the Notifier in block A.2 (see subsection 6.2.1.2) and not as the “Canadian Agent”; in that case, block A.4 would be blank. The Third Party Information Supplier may be identified in block A.5 if he or she is supplying proprietary confidential information to complete the NSN (see subsection 6.2.1.7).

1.4.3 Toll Manufacturer

Toll manufacturing occurs when a company contracts a manufacturer to process its raw materials and create a new substance. Ownership of the raw materials and resulting substance remains with the contracting company throughout the activity. For new substances that are manufactured on toll, the contracting company is designated as the notifier. If any actions are taken as a result of the assessment, the notifier must inform the toll manufacturer of these actions and the toll manufacturer is responsible for complying with these actions.

1.5 When to Submit a New Substances Notification to the New Substances Program

The timing of an NSN depends on the notification group (Schedule, which prescribes the assessment period) and when the quantity specified by the Schedule (trigger quantity) is likely to be exceeded.

1.5.1 New Substances Notification Assessment Periods

Assessment periods range from 5 to 75 calendar days, depending on the type and amount of the substance being manufactured or imported (see section 4). NSNs must be provided prior to the number of calendar days prescribed and in advance of the trigger quantity being exceeded. These are shown in Table 1-1.

Table 1-1 Schedule Numbers, Assessment Periods and Quantities Triggering the Requirement for New Substances Notifications for Chemicals and Polymers

Schedule[a]	Explanation	Assessment Period (days)	Annual quantities (kg)
Chemicals			
1	Special category[b] – NDSL[c] and not on NDSL	30	1 000
	Update of information	30	10 000
4	Not on NDSL	5	100
4	NDSL	30	1 000
5	Not on NDSL	60	1 000
5	NDSL	60	10 000
	NDSL – high release/significant public exposure[d]	75	50 000
6	Not on NDSL	75	10 000
Polymers			
3	Special category[b]– NDSL and not on NDSL	30	10 000
9	All polymers	30	1 000
10	Non-RRR polymers[e] either on NDSL or all reactants on DSL/NDSL	60	10 000
	Non-RRR polymers[e] either on NDSL or all reactants on DSL/NDSL – high release/significant public exposure[d]	60	50 000
11	Non-RRR polymers[e] not on NDSL and not all reactants on DSL/NDSL	60	10 000

[a] Additional information is required from Schedule 2 if the substance is a biochemical or biopolymer for all notified substances (see sections 4.2 through 4.9).

[b] Special categories include research and development, contained site-limited intermediate and contained export-only substances (see section 4).

[c] NDSL – Non-domestic Substances List

[d] There may be an additional assessment period for substances that exceed 50 000 kg/year if they meet one of the following criteria: releases anticipated to exceed 3 kg/day into the aquatic environment after wastewater treatment; or significant public exposure (see section 4.4.3 or 4.9.2). If these criteria are not met, then Schedule 5 or 10 is the final requirement.

[e] Non-RRR polymers – Non-reduced Regulatory Requirement Polymers (see section 3.3.1.6).

1.5.2 New Substances Notification Fees

The *New Substances Fees Regulations* (NSFR) were developed to incorporate service fees; these fees must be provided with most NSNs submitted under the Regulations. The amount of fees required is dependent on the amount of annual sales in Canada for the notifier, the specific Schedule being submitted and other services being requested (e.g., confidential search on the DSL or Non-domestic Substances List (NDSL) or masked name application). A fee schedule for different levels of service is provided on the NSN fees webpage.[6] Additional information can also be found in the NSFR.

Fee reductions are available for notifiers meeting the criteria for small- or medium-sized enterprises (see NSN fees webpage[6]) and for matched or consolidated notifications, as described in sections 5.1 and 5.3 of this Guidance Document, respectively.
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1.5.3 New Substances Not Subject to the Notification Fees

The NSFR do not apply to biochemicals, biopolymers, research and development substances or to substances that are intended solely for use in products regulated under any other Act of Parliament, including the *Food and Drugs Act* (F&DA), the *Fisheries Act* and the *Health of Animals Act*.

The fees also do not apply to SNANs (see sections 1.3 and 9.6.2), to the submission of the update of information at 10 000 kg/yr required for special category Schedule 1 notification (see section 4.2.2) and to the submission of additional information at 50 000 kg/yr for substances that have high release or significant public exposure (see sections 4.4.3 and 4.9.2).

1.6 Enforcement

For information about the enforcement of the Act and the Regulations, notifiers should consult The Compliance and Enforcement Policy (https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/compliance-enforcement-policy.html). This policy was established to ensure that the Act is applied throughout Canada, fairly, predictably and consistently.

[6] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

SECTION 2 — THE INVENTORIES

2.1 Role of the Domestic Substances List

The term “Domestic Substances List” (DSL) is used in this Guidance Document to specify substances listed both publicly and confidentially on the inventory.

For a comprehensive description of each part of the DSL, consult Appendix 12 of this Guidance Document.

2.1.1 The Domestic Substances List – Definition of a New Substance

The DSL provides an inventory of substances manufactured in, or imported into Canada on a commercial scale. A substance not on the DSL is therefore a new substance in Canada. The DSL is the sole basis for determining whether a substance is new for the purposes of *the Canadian Environmental Protection Act, 1999* (the Act) and the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations). Substances are added to the DSL using a unique substance identifier (e.g., a Chemical Abstracts Service Registry Number (CAS registry number)[7]).

Substances on the DSL are not subject to notification unless they are followed by a regulatory flag (i.e. S flag. S prime flag, or P flag) as these flags after a substance identifier indicate that the substance is subject to notification under certain circumstances (see section 2.1.4.1). The DSL includes the original list, published in the *Canada Gazette*, Part II, on May 4, 1994, and all additions or deletions subsequently published in the *Canada Gazette*, Part II.

For a comprehensive listing of substances that are subject to SNAc requirements, see SNAc Publications under the Act, which is published on the Open Government Portal website at https://open.canada.ca/data/en/dataset/bfab5876-77e5-4dbf-8693-3b0bc69428b8.

Although care has been taken to ensure that the information in this list accurately reflects the requirements prescribed in the Act, you are advised that, should any inconsistencies be found, the legal documents, published in the *Canada Gazette*, will prevail.

2.1.2 Confidential Substances on the Domestic Substances List

A notifier may request that the substance they notify be added confidentially to the DSL using a masked name that complies with the *Masked Name Regulations*. A Third Party

[7] The Chemical Abstracts Service Registry Number (CAS registry number) is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and reports are required by law or administrative policy, is not permitted without the prior written permission of the American Chemical Society.

Information Supplier who requests that substance information be kept confidential from the notifier may also request that a substance be added confidentially to the DSL. A substance eligible for addition to the DSL under a masked name will be assigned a Confidential Substance Identity Number[8] even when a CAS registry number is available. The Confidential Substance Identity Number will be provided to the notifier or the Third Party Information Supplier by the New Substances (NS) program. Once eligible, the Confidential Substance Identity Number and acceptable masked name for the substance will be published in the *Canada Gazette*, Part II. Substances listed confidentially on the DSL are treated the same as substances listed publicly on the DSL.

The NS program conducts a search for all substances that have been notified as confidential to verify whether those substances are on any public chemical inventory, such as the Non-domestic Substances List (NDSL), the United States Environmental Protection Agency's (US EPA) *Toxic Substances Control Act* (TSCA) Chemical Substances Inventory, the Australian Inventory of Chemical Substances (AICS), the Korean Existing Chemicals List (ECL) or the European Inventory of Existing Commercial Substances (EINECS). If the substance is listed on any of these public inventories, the notifier will be informed of that fact and will be required to provide, within 20 days, further justification for his or her confidentiality request (see section 2.1.2.1). If the supporting documentation is deemed to be inadequate, the notifier will be informed that the NS program intends to publish the appropriate CAS registry number (see section 6.2.1.16) on the DSL. The notifier will have the opportunity to appeal this decision before the information is published.

2.1.2.1 Justification for Masking a Substance Listed on a Public Inventory

If the NS program finds that the substance is listed on at least one public inventory, such as those mentioned above, the notifier will be asked to provide a justification, explaining why the information should be treated as confidential. This justification should be selected from the following criteria:

a) the substance identity is a trade secret of the submitter;
b) the substance identity is of a financial, commercial, scientific or technical nature that is treated consistently in a confidential manner by the submitter;
c) the disclosure of the substance identity could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, the submitter; or
d) the disclosure of the substance identity could reasonably be expected to interfere with contractual or other negotiations of the submitter.

The information to be provided must also include the information set out in section 7.2.2 of this Guidance Document when claiming substance identity as confidential.

[8] Also referred to as a Confidential Accession Number by the program.

Subsection 315(1) of the Act states that the Minister of the Environment (the Minister) may, however, disclose information where

a) the disclosure is in the interest of public health, public safety or the protection of the environment; and

b) the public interest in the disclosure clearly outweighs in importance:

   i) any material financial loss or prejudice to the competitive position of the person who provided the information or on whose behalf it was provided, and
   ii) any damage to the privacy, reputation or human dignity of any individual that may result from the disclosure.

2.1.3 Amendments to the Domestic Substances List

As a result of statutory requirements, the DSL is amended from time to time for the following reasons:

a) nomination of a substance to the DSL that was manufactured in or imported into Canada between January 1, 1984, and December 31, 1986 (subsection 66(1) of the Act);

b) all prescribed or additional information as well as tests results has been provided to the Minister; the Minister of the Environment and the Minister of Health are satisfied that the substance has been imported or manufactured in Canada by the person who provided the information; an assessment of the substance has been performed under section 83 and no conditions imposed by the Minister under paragraph 84(1)(a) concerning the manufacture or import of the substance remain in effect (subsection 87(1) or 87(5) of the Act); or

c) to maintain the list, for instance by making correction to a substance identifier, when required (subsection 66(1) of the Act).

Amendments to the DSL are published in the *Canada Gazette*, Part II, approximately every six to eight weeks.

For additional information about the eligibility requirements for adding substances to the DSL, see section 10.2.1 of this Guidance Document.

2.1.4 Domestic Substances List Flags

The DSL contains five different flags for substances; however, depending on different situations some flags can be combined. Some of the flags are used for governmental tracking purposes, and others are used to indicate to notifiers that additional notification requirements may be necessary for the substance being manufactured or imported. The onus is on the notifier to search for flags and for any regulations that may be imposed on a substance that may necessitate additional notification requirements. The notifier

may contact the Substances Management Information Line to determine whether additional notification requirements are necessary.

2.1.4.1 Regulatory Flags

The following three regulatory flags indicate to notifiers that additional notification requirements may be necessary prior to manufacturing or importing a specific substance:

- **The S flag**: The letter S after a substance identifier indicates that the substance is subject to subsection 81(3) of the Act. This flag is used for a new substance that was assessed under section 83 of the Act and the assessment concluded that a SNAc, in relation to the substance, may result in the substance becoming toxic according to the Act. When the substance was added to the DSL it was added with an S flag.

- **The S′ (S prime) flag**: The letter S′ after a substance identifier indicates that the substance is subject to subsection 81(3) of the Act. This flag is used for a substance that was assessed under sections such as 68 or 74 of the Act where the assessment concluded that a SNAc, in relation to the substance, may result in the substance becoming toxic according to the Act. The DSL was then updated to include the S′ after a substance identifier.

The purpose of the S and S′ flags is to indicate that information respecting the flagged substance must be submitted if the substance is proposed for a SNAc. Anyone proposing a SNAc must provide the Minister with the prescribed information in the prescribed timeframe prior to the commencement of the proposed SNAc. This new information will allow the NS program to assess the environmental and human health risks associated with the SNAcs, and modify the SNAc requirements, or to further develop risk management measures, if deemed necessary (see section 9.6.2).

- **The P flag**: The letter P after a substance identifier indicates that the substance, which was subject to subsection 81(1) or 81(2) of the Act, was assessed and added to the DSL on the basis that it met the Reduced Regulatory Requirement (RRR) polymer criteria (see section 3.3.1.5).

The purpose of the P flag is to indicate that a Non-reduced Regulatory Requirement (non-RRR) Schedule 9 New Substances Notification (NSN) for the flagged polymer must be submitted if anyone, including the original notifier, manufactures the polymer in Canada or imports it into Canada in a form that no longer considered RRR.

In the case where the NS program assesses the re-notified substance and concludes that there is no suspicion of toxicity for the non-RRR polymer and it is again eligible for addition to the DSL, the DSL will be updated accordingly, and the P flag will be removed. In the case where the NS program assesses the non-RRR form of the polymer and concludes that there is a suspicion of toxicity, appropriate actions (see section 9.6) will be taken post-assessment.

2.1.4.2 Administrative Flags

The following two administrative flags are used by the NS program to identify substances added to the DSL under specific scenarios:

- **The T flag**: The letter T after a substance identifier indicates that the substance was manufactured or imported during the transitional period (i.e. between January 1, 1987, and July 1, 1994) and the prescribed information was provided to and assessed by the NS program in accordance with subsection 81(2) and section 83 of the Act, respectively.

- **The N flag**: The letter N after a substance identifier indicates that the substance was added to the DSL based on the substance being manufactured or imported into Canada after July 1, 1994, and the prescribed information was provided to and assessed by the Minister in accordance with subsection 81(1) and section 83 of the Act, respectively.

When there is no flag associated with a substance that is listed on the DSL, the substance was added to the list via a nomination of the substance under section 66 of the Act (see section 2.1.3).

2.2 Role of the Non-domestic Substances List

2.2.1 The Non-domestic Substances List

The term NDSL is used in this Guidance Document to specify substances listed both publicly and confidentially on the NDSL inventory.

The NDSL is a list of substances that are not used commercially in Canada above the trigger quantities specified in the Regulations, but that are known to be in international commerce. Substances on the NDSL are subject to the notification requirements set out in the Regulations; however, they are subject to fewer information requirements in comparison to new substances that are not on the NDSL.

For a comprehensive description of each part of the NDSL, consult Appendix 12 of this Guidance Document.

2.2.2 Confidential Substances on the Non-domestic Substances List

A notifier may request that the substance he or she is notifying be added confidentially to the NDSL using a masked name that complies with the *Masked Name Regulations*. A substance eligible for addition to the NDSL under a masked name (see section 2.2.3.2) is assigned a Confidential Substance Identity Number, whether a CAS registry number is available or not. This Confidential Substance Identity Number will be provided to the notifier by the NS program. Once the substance is determined to be eligible, its Confidential Substance Identity Number and acceptable masked name will be published in the *Canada Gazette*, Part I. Once the substance has been officially and confidentially

added to the NDSL, the substance will be treated the same way as a substance listed publicly on the NDSL. As such, it is subject to fewer information requirements. The Confidential Substance Identity Number should be used to identify the substance for all future notification purposes.

The NS program conducts a search for all substances that have been notified as confidential to verify whether those substances are on any public chemical inventory, such as the DSL, the US EPA's TSCA Inventory, the AICS, the ECL or the EINECS. If the substance is listed on any of these public inventories, the notifier will be informed of that fact and will be required to provide, within 20 calendar days, further justification for his or her request for confidentiality (see section 2.1.2.1). If the supporting documentation is deemed to be inadequate, the notifier will be informed that the NS program intends to publish the appropriate CAS registry number on the NDSL (see section 6.2.1.16). The notifier will have the opportunity to appeal this decision before the information is published.

2.2.3 Amendments to the Non-domestic Substances List

As a result of statutory requirements, the NDSL is amended from time to time for the following reasons:

a) annual updates based on the US EPA's TSCA Inventory;
b) nomination of a substance to the NDSL through submission of a Nomination Form – NDSL;
c) DSL amendments (substances on the NDSL are deleted from this list when they are added to the DSL); and
d) to maintain the list, for instance by making correction to a substance identifier, when required. Amendments to the NDSL are published in the *Canada Gazette*, Part I, approximately every six to eight weeks.

2.2.3.1 Updates Based on the US EPA's TSCA Chemical Substances Inventory

The NDSL is based on substances that have been on the public portion of the US EPA's TSCA Inventory for a minimum period of one year. Updates to the NDSL, based on the US EPA's TSCA Inventory, will be published annually in the *Canada Gazette*, Part I. Certain substances on the TSCA Inventory are not added to the NDSL, including those subject to risk management controls in Canada or the U.S., or to the *Stockholm Convention on Persistent Organic Pollutants* or the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*.

2.2.3.2 Nominating a Substance to the Non-domestic Substances List

Substances on the confidential portion of the US EPA's TSCA Inventory are not automatically added confidentially to the NDSL in the annual update process. Substances will be added confidentially to the NDSL or publicly to the NDSL only after a person provides the appropriate information required in a Nomination Form, including

documentation demonstrating that the substance has existed on the confidential portion of the US EPA's TSCA Inventory for at least one year. In the event that a notifier wishes to have the substance added publicly to the NDSL, a Nomination Form must be provided with a statement indicating that the substance identity is not considered confidential business information. Instructions for nominating substances to the NDSL can be found on the Nomination Form. The form can be obtained from the NS program website at https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notification-forms.html or by contacting the Substances Management Information Line. There are no prescribed deadlines for adding substances that become eligible for addition to the NDSL through the annual update, or submittal of a Nomination Form.

Although there are no fees associated with nominating a substance to the NDSL, there is a fee for the "masked name application" (see fee table on the NSN fees webpage[9]) when substances are added confidentially to the NDSL.

2.3 Determining the Presence of Substances on Inventories

To find out whether a substance is on the DSL or on the NDSL, the substance name, the CAS registry number, the Confidential Substance Identity Number (if available) or the Enzyme Commission (International Union of Biochemistry and Molecular Biology (IUBMB)) number can be entered into the search engine located on the NS program's website at https://pollution-waste.canada.ca/substances-search/Substance?lang=en.

If the Confidential Substance Identity Number is unknown and the notifier wishes to determine whether the substance is confidentially listed on either the DSL or the NDSL, a Notice of *Bona Fide* Intent to Manufacture or Import the substance (see section 2.3.1) must be filed to the NS program. The CAS registry number or Confidential Substance Identity Number can also be provided directly to the CAS, which will, for a fee, search all inventories for that substance (for more information about the CAS, see Appendix 4).

It is important to note that the search engine does not show any flags. The onus is on the notifier to consult the *Canada Gazette* publication to ensure that there are no flags associated with a particular substance. (For more information about the flags, see section 2.1.4).

2.3.1 Notice of Bona Fide Intent to Manufacture or Import

Substances listed confidentially on the DSL or NDSL are published with Confidential Substance Identity Numbers using masked identities that are named in a manner prescribed by the *Masked Name Regulations*. Any person who intends to manufacture, import or use a substance may seek confirmation that the substance is listed confidentially on either of these lists from the NS program by providing a Notice of *Bona Fide* Intent to Manufacture or Import the substance.

[9] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

A Notice of *Bona Fide* Intent to Manufacture or Import must include the following information and must be submitted to the NS program at the address provided in the Comments and Inquiries section at the beginning of this Guidance Document:

a) the specific chemical identity of the substance established in accordance with the nomenclature rules of the International Union of Pure and Applied Chemistry (IUPAC), CAS, or IUBMB;
b) the CAS registry number or Enzyme Commission number (IUBMB) (if available);
c) a statement, signed by a person residing in Canada, declaring that the person intends to manufacture, import or use the substance and that the substance would be subject to notification if it is not on the DSL;
d) if the manufacture of the substance occurs in Canada, a description of the research and development activities conducted to date (e.g., information such as manufacturing procedures, quantities manufactured, types of data generated on the substance and manufacturing history in international commerce) and the intended use of the substance;
e) if the substance is imported, a description of the manufacturing history of the substance in international commerce (if known);
f) an elemental analysis;
g) valid spectral analysis or analyses that confirm(s) the identity of the substance; and
h) the applicable fee (see fee table on the NSN fees webpage[10]).

If a notifier who wants to import a substance is unable to supply all of the required information because a Third Party Information Supplier considers this information confidential, the notifier is required to ensure that the Third Party Information Supplier submits the confidential information directly to the NS program.

After the notifier has provided a Notice of *Bona Fide* Intent to Manufacture or Import the substance, the NS program will search substances confidentially listed on the DSL and NDSL, and will indicate, within 15 days of receipt of the complete documentation, whether the substance is on either of the lists. Note that there are fees associated with a Notice of Bona Fide Intent to Manufacture or Import (see fee table on the NSN fees webpage[10]).

2.3.2 Copies of the Domestic Substances List and Non-domestic Substances List

The DSL and the NDSL are available to view online or export to Excel (xlsx) using the search engine: https://pollution-waste.canada.ca/substances-search/Substance?lang=en. Chemicals, biochemicals, polymers and biopolymers are listed by their respective CAS registry number, while biochemicals that are enzymes are listed by CAS registry number registry number or Enzyme Commission numbers designated by the IUBMB. Confidential substances are listed under their respective Confidential Substance Identity Number and masked identities that are named in a

[10] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

manner prescribed by the *Masked Name Regulations* (see section 7). These lists are amended several times per year and notifiers should consult them regularly (see sections 2.1.3 and 2.2.3).

SECTION 3 — SUBSTANCES

3.1 Definition of "Substance"

For the purposes of the New Substances Notification regime, section 3 of the *Canadian Environmental Protection Act, 1999* (the Act) defines a "substance" as

> any distinguishable kind of organic or inorganic matter, whether animate or inanimate, and includes
>
> (*a*) any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformations in the environment;
>
> (*b*) any element or free radical;
>
> (*c*) any combination of elements of a particular molecular identity that occurs in nature or as a result of a chemical reaction; and
>
> (*d*) complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not practicably be formed by simply combining individual constituents.

In some instances, materials derived from natural sources and complex reactions are considered single substances for notification purposes. These materials are commonly referred to as **U**nknown or **V**ariable composition **C**omplex reaction products or **B**iological materials (UVCBs) and are considered a single substance for notification purposes.

3.2 Substances Not Subject to Notification

Substances referred to in sections 3.2.1 to 3.2.11 of this Guidance Document do not require notification under the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations).

3.2.1 Mixtures

According to subsection 3(1) of the Act,

> any mixture that is a combination of substances and does not itself produce a substance that is different from the substances that were combined

is excluded from the definition of ''substance'' for the purpose of the new substances and Significant New Activity (SNAc) provisions of the Act and consequently, does not require notification.

An example of a mixture is saline water where sodium chloride crystals were dissolved in water.

Note: If any constituent of a mixture is a new substance, that constituent may be subject to notification.

Note: Some substances, such as UVCBs, that are usually derived from natural sources or reactions are considered a single substance and may be subject to notification whether well characterized in terms of individual constituents or not (see section 3.3.1.3).

Other types of mixtures not subject to notification are:

a) **Hydrates**: Hydrates of a substance or hydrated ions formed by association of a substance with water are considered to be a mixture of that substance and water. Therefore, if the anhydrous form is listed on the Domestic Substances List (DSL), hydrated forms are not notifiable substances. An example of an anhydrous substance that is listed on the DSL is carbonic acid, magnesium salt (1:1) (Chemical Abstracts Service Registry Number (CAS registry number) 546-93-0); therefore, the hydrated form $MgCO_3 \cdot nH_2O$ is not notifiable.

Note: Metallic hydroxides, often termed metal hydrates, do not contain water of hydration and are *not* considered hydrates for notification purposes. Such substances must be notified if not on the DSL. An example of a metal hydroxide is copper hydroxide, $Cu(OH)_2$.

b) **Homogeneous and Heterogeneous Alloys**: Homogeneous and heterogeneous alloys are considered mixtures and should not be notified. Alloys that are solid or liquid mixtures of two or more metals or are mixtures of one or more metals with certain non-metallic elements (e.g., certain carbon steels) are considered mixtures and are not notifiable. An example of a homogeneous alloy is copper, compound with zinc (CuZn); an example of a heterogeneous alloy is copper, compound with cobalt (CuCo). Intermetallic compounds of well-defined stoichiometry are not considered alloys and should be notified. An example of an intermetallic compound is intermetallic tin ($In–^{49}Sn$).

3.2.2 Manufactured Items

According to subsection 3(1) of the Act,

> any manufactured item that is formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design.

is excluded from the definition of ‘’substance’’ for the purposes of the new substances and SNAc provisions of the Act and consequently, does not require notification.

Note: While manufactured items described above are not subject to notification, if a substance is intended to be released from a manufactured item, the substance may be subject to notification. The release of a substance is considered to be intended if it occurs during use of the manufactured item and the release contributes to a function of the manufactured item. The transfer of substances from a manufactured item to storage vessels during maintenance is not considered a release that contributes to a function of the item.

Table 3-1 Examples of Manufactured Items Containing Substances Intended to be Released from the Manufactured Item

Manufactured Item (not subject to notification)	Substance intended to be released from the Manufactured Item (subject to notification)
Electric air freshener diffuser	Substances intended to be emitted from the air freshener diffuser, such as fragrances, solvents, etc.
Personal care wipes	Substances intended to be delivered by the wipes such as surfactants, fragrances, etc.
Deodorant/antiperspirant container/delivery device	Substances intended to be released by the deodorant/antiperspirant container/delivery device such as antimicrobials, chelating agents, propellants, fragrances, etc.
Writing instruments (e.g., pens, dry-erase markers)	Substances intended to be released from the writing instrument (components of the ink) such as pigments, dyes, solubilizing agents, solvents, fragrances, etc.
Printer cartridge	Substances intended to be released from the cartridge (components of the ink or toner) such as antistatic agents, pigments, etc.
Dryer sheets	Substances intended to be released during use such as fragrances, antistatic substances, etc.
Pre-loaded syringe	Substances intended to be delivered by the syringe such as pharmaceutically active and non-active ingredients.
Lipstick container or dispenser	Substances intended to be delivered by the lipstick container or dispenser such as pigments, emollients, etc.

Motor vehicle	Substances intended to be released such as substances in windshield washer fluid.

Table 3-2 Examples of Manufactured Items Containing Substances that may be Released from a Manufactured Item, but the Release is not Intended

Manufactured Item (not subject to notification)	Substances not intended to be released from the Manufactured Item (not subject to notification)
Electronic devices (e.g., computer)	Substances such as flame retardants that are not intended to be released from the device's casing (any release of such a substance would not contribute to a function of the item).
Textiles (e.g., carpet, towels, clothing)	Substances such as stain repellents and dyes that are not intended to be released from the textile (any release of such a substance would not contribute to a function of the item).
Motor vehicle	Substances such as lubricants, antioxidants, etc. in crankcase oil that are not intended to be released from the motor vehicle (any release of such a substance would not contribute to a function of the item). The transfer of substances from a vehicle to storage vessels during maintenance, e.g., oil changes, is not considered a release that contributes to a function of the item.

3.2.3 Wastes

According to subsection 3(1) of the Act,

> any animate matter that is, or any complex mixtures of different molecules that are, contained in effluents, emissions or wastes that result from any work, undertaking or activity

is excluded from the definition of ''substance'' for the purposes of the new substances and SNAc provisions of the Act and consequently, does not require notification.

Note: If a material described above is isolated and commercialized and is not on the DSL, it may be subject to notification under the Regulations.

3.2.4 Other Acts of Parliament

According to paragraph 81(6)(a) of the Act and subsection 3(1) of the Regulations, the Regulations and the SNAc provisions of the Act do not apply in respect of

> a substance that is manufactured or imported for a use that is regulated under any other Act of Parliament that provides for notice to be given before the manufacture, import or sale of the substance and for an assessment of whether it is toxic or capable of becoming toxic.

Consequently, a substance that is manufactured or imported for a use that is regulated under any act or regulation listed in Schedule 2 of the Act does not require notification.

Note: Substances excluded from the scope of the other Acts of Parliament or regulations listed in Schedule 2 of the Act may be subject to notification under the Regulations. This includes isolated reaction intermediates, feedstocks and other starting materials used in the manufacture of any new substance.

Notifiers of new substances intended for uses regulated under other Acts of Parliament or regulations should monitor federal government websites (https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry.html) and the *Canada Gazette* to determine whether the use for the substance remains under the jurisdiction of other Acts of Parliament or Regulations.

Substances that are subject to more than one Act of Parliament or regulation must be in compliance with the requirements of those Acts of Parliament or regulations. For example, a substance used in a pesticide product that is regulated under the *Pest Control Products Act* may also have non-pesticidal applications that could be subject to the *Canadian Environmental Protection Act, 1999* and the *New Substances Notification Regulations (Chemicals and Polymers)*.

3.2.5 Transient Reaction Intermediates

According to paragraph 81(6)(b) of the Act, the Regulations and the SNAc provisions of the Act do not apply in respect of

> transient reaction intermediates that are not isolated and are not likely to be released into the environment

and consequently, these do not require notification.

Transient reaction intermediates are substances produced within a sequence of chemical reactions between the starting materials and the end product and are

a) contained in a reaction vessel or a closed manufacturing system (including process holding tanks) located within a single building or single process area;
b) intended to be fully consumed in the course of the chemical reaction;

c) part of an uninterrupted manufacturing process (e.g., at any one time, starting materials or intermediates within the reaction sequence are being processed, except in the event of an unscheduled shutdown); and
d) not likely to be released into the environment during normal operations, and measures are in place to minimize releases during accidental breaches of the closed manufacturing system.

Notifiers are advised to maintain technical data (process and environmental release information) to support claims that a substance is a transient reaction intermediate as described above.

3.2.6 Impurities

According to paragraph 81(6)(c) of the Act, the Regulations and the SNAc provisions of the Act do not apply in respect of

> impurities, contaminants and partially unreacted materials, the formation of which is related to the preparation of a substance

and consequently, these do not require notification.

Impurities and contaminants are substances that are normally found in minimal concentrations in the starting materials or are the result of secondary reactions that occur during the manufacturing process. These substances and partially unreacted starting materials that are present in the final product are the direct result of the preparation, are not necessary to the end-use of the product, have not been intentionally added to the substance, and do not enhance the value of the substance.

3.2.7 Incidental Reaction Products

According to paragraph 81(6)(d) of the Act, the Regulations and the SNAc provisions of the Act do not apply in respect of

> substances produced when a substance undergoes a chemical reaction that is incidental to the use to which the substance is put or that results from storage or from environmental factors

and consequently, these do not require notification.

Examples of incidental reaction products include substances formed from chemical reactions during

a) exposure to environmental factors such as air, moisture, microbial organisms and sunlight (substances produced from deliberate reactions with water may be subject to notification, e.g., metal hydroxides formed from a metal oxide and water);
b) storage (e.g., partial polymerization of drying oils);
c) the intended use of a substance or mixture containing it (e.g., adhesives, paints, cleansers, combustion products from fuels, fuel additives and water softeners); and

d) the blending of a formulation when there is no intention to produce new substances and any ensuing chemical reactions do not enhance the value of the formulation (e.g., blending monomers to a precise ratio for customer convenience would not result in a notifiable substance even if some reactions occurred; however, intentional manufacture of a pre-polymer to satisfy a customer's processing specifications would produce a notifiable substance).

3.2.8 Low-Quantity Exemptions

According to paragraph 81(6)(e) of the Act, the Regulations and the SNAc provisions of the Act do not apply in respect of

> a substance that is manufactured, used or imported in a quantity that does not exceed the maximum quantity prescribed

and consequently, such a substance does not require notification.

The Regulations do not apply to substances manufactured or imported in a quantity that does not exceed the prescribed quantity (i.e., trigger quantity) to provide information under the Regulations. The specific quantities that trigger notification requirements under the Regulations can be found in Table 1-1 of this Guidance Document.

3.2.9 Substances Carried through Canada

According to subsection 3(2) of the Regulations, these do not apply in respect of

> a substance that is loaded on a carrier outside Canada and moved through Canada to a location outside Canada, whether or not there is a change of carrier during transit.

Consequently, such a substance does not required notification under the Regulations.

Note: If a substance is brought into Canada and stored for subsequent distribution, the substance may be subject to notification.

3.2.10 Polymers on the Domestic Substances List modified by less than or equal to 2% by weight

A polymer on the DSL that is modified by adding reactants, none of which constitutes more than 2% by weight of the polymer, does not require the specific substance name to be changed and is therefore not subject to notification. The term "modified" refers to the amount of additional reactant that has been incorporated into the structure of the polymer or the amount charged to the vessel.

Note: The specific substance name and CAS registry number identify a specific substance, and therefore a name or CAS registry number change may result in the substance being subject to notification.

For biopolymers, monomer units and reactants are considered to be the repeating units within the polymeric substance, which are produced *in situ* by the micro-organism or are added to the reaction vessel.

3.2.11 Substances Occurring in Nature

The New Substances (NS) program considers that substances occurring in nature are not subject to notification. These substances are defined as naturally occurring and must be:

- unprocessed;
- processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, or by heating solely to remove water; or
- extracted from air by any means.

The criteria for substances occurring in nature limits inclusion only to those substances derived from nature (including the land, water, atmosphere and life forms which naturally inhabit the Earth) by means specified. The interpretation of the criteria is **literal** and **strict**. For example, distillation is not considered a mechanical process, and dissolution in solvents other than water does not fall within this definition.

3.3 Substances Subject to Notification

Notification is required pursuant to section 81 of the Act in relation to the following:

a) substances new to Canada (i.e., those not on the DSL) that are manufactured in Canada or imported into Canada ; and
b) substances used to undertake a significant new activity (see section 9.6).

3.3.1 Classification of Substances

For the purposes of the Regulations, new substances are grouped into two major classes, each subject to its own specific information requirements. These classes are non-polymeric substances (referred to in this Guidance Document as chemicals and biochemicals) and polymeric substances (referred to in this Guidance Document as polymers and biopolymers). This document describes the notification requirements and processes for chemicals, biochemicals, polymers and biopolymers (including UVCB substances and nanomaterials).

3.3.1.1 Chemicals and Biochemicals

The information requirements for chemicals and biochemicals are prescribed in the Regulations and apply to all substances subject to notification that are neither polymers nor living organisms. The term “biochemical”, means a chemical that is produced by a micro-organism, or means a protein or a nucleic acid derived from a plant or an animal (refer to subsection 1(1) of the Regulations). Note that chemicals derived from a whole plant or animal or from parts of a whole plant or animal are not biochemicals for the

purpose of the Regulations. An example of a biochemical is the enzyme subtilisin produced by *Bacillus subtilis*.

> **Note**: The production organism of a biochemical may be subject to the *New Substances Notification Regulations (Organisms)* if it is a new living organism as defined in section 104 of the Act.

3.3.1.2 Polymers and Biopolymers

Polymers are defined in subsection 1(1) of the Regulations as substances that consist of

a) molecules characterized by the sequence of one or more types of monomer units;
b) greater than 50% by weight of molecules having three or more monomer units that are covalently bound to one or more other monomer units or reactants;
c) less than 50% by weight of molecules of the same molecular weight; and
d) molecules distributed over a range of molecular weights whose differences in molecular weights are primarily attributable to differences in the number of monomer units.

The term “biopolymer” means a polymer that is produced by a micro-organism, or means a protein or a nucleic acid derived from a plant or an animal (refer to subsection 1(1) of the Regulations). For biopolymers, monomer units and reactants are considered to be the repeating units within the polymeric substance, which are either produced *in situ* by the micro-organism or added to the reaction vessel. An example of a biopolymer is the polysaccharide xanthan gum, produced by *Xanthomonas camprestris*.

> **Note**: The production organism of a biopolymer may be subject to the *New Substances Notification Regulations (Organisms)* if it is a new living organism as defined in section 104 of the Act.

3.3.1.3 Unknown or Variable composition Complex reaction products or Biological materials

A UVCB substance is considered a single substance for notification purposes. There are many different types of UVCB substances. Generally, they have the following characteristics[11]:

a) they contain numerous chemicals and cannot be represented by a simple chemical structure or defined by a specific molecular formula;

[11] OECD (2014). Guidance Document on the Grouping of Chemicals, OECD Environment Health and Safety Publications. Series on Testing and Assessment. No. 194 (ENV/JM/MONO(2014)4) (http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en)

b) they are not intentional mixtures of chemicals;

c) many are of natural origin (e.g., crude oil, coal, plant extracts, reaction products) and cannot be separated into their constituent chemical species;

d) the concept of “impurities” typically does not apply to complex substances; or

e) they are often produced according to a performance specification related to their physico-chemical properties.

If the notified substance does not meet the polymer definition and falls into the UVCB category, it must be notified using the information requirements for chemicals.

3.3.1.4 Nano-Scale Substances (referred to as Nanomaterials)

The NS program is currently using the Health Canada Working Definition of Nanomaterials as the basis for identifying nanomaterials (https://www.canada.ca/en/health-canada/services/science-research/reports-publications/nanomaterial/policy-statement-health-canada-working-definition.html). Based on this definition, a substance is classified to be nanomaterial if it is a manufactured substance and:

a) it is at or within the nanoscale in at least one external dimension, or has internal or surface structure at the nanoscale, or;
b) it is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena.

For the purposes of this definition:

a) the term "nanoscale" means 1 to 100 nanometres, inclusive;
b) the term "nanoscale properties/phenomena" means properties which are attributable to size and their effects; these properties are distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material; and
c) the term "manufactured" includes engineering processes and the control of matter.

More details on these terms can be found in the working definition.

In order to provide greater regulatory clarity, the NS program will evaluate a substance as a nanomaterial if it meets the criteria described in the Working Definition of Nanomaterials and has 10% or more of its primary particle distribution by number in the nanoscale range (1 to 100 nanometres, inclusive). The 10% by number threshold is consistent with reporting requirements used in a 2015 information-gathering survey for nanomaterials.[12] Alternatively, if a particle size distribution by number is not available,

[12] Guidance for responding to the Notice with respect to certain nanomaterials in Canadian Commerce https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=AACFB2C0-1

the NS program will evaluate a substance as a nanomaterial if it meets the criteria described in the Working Definition of Nanomaterials and at least 1% (by mass) of the particles are in the nanoscale range. The use of 1% (by mass) as particle size distribution threshold is in line with the United States Environmental Protection Agency's (US EPA) final rule for *Toxic Substances Control Act* (TSCA) reporting and recordkeeping requirements for nanoscale materials.[13]

In order to better account for the presence of smaller nanoscale particles, it is also recommended that the particle size distribution be measured by number count, rather than by mass or volume. For size characterization of nanomaterials, using a single method may not accurately represent the overall size distribution. Therefore, using a combination of measurement methods to determine the overall particle size distribution is recommended (see Appendix 10).

The DSL is the sole basis for determining whether a substance is new for the purposes of the Act. Substances on the DSL that can be made at the nanoscale are not subject to notification whereas those not listed on the DSL are considered to be new to Canada and are subject to the Regulations.

For additional details on nanomaterials, see Appendix 10.

3.3.1.5 Reduced Regulatory Requirement Polymers

Reduced Regulatory Requirement (RRR) polymers are polymers that meet specific criteria concerning molecular weight, oligomer content, elemental composition, stability and relative amounts of cationic and reactive functional groups. These criteria are listed in paragraph 9(a) to (c) as well as in items 1 to 5 of Schedule 7 of the Regulations (see Appendix 2). RRR polymers are subject to the notification requirements set out in the Regulations; however, they are subject to fewer information requirements in comparison to Non-reduced Regulatory Requirement (non-RRR) polymers (see section 4.8).The letter ''P'' after identifier of a substance on the DSL (see section 2.1.4.1) indicates that the substance was assessed and added on the basis that it met the RRR polymer criteria.

Section 9 of the Regulations describes RRR polymers as one of the following:

a) a polymer that is not one of the types listed in items 1 to 4 of Schedule 7 of the Regulations (see section 3.3.1.7) and that has a number average molecular weight greater than 10 000 daltons, with less than 2% of its components having molecular weights less than 500 daltons and less than 5% of its components having molecular weights less than 1 000 daltons;

[13] US EPA. 2017. Chemical substances when manufactured or processed as nanoscale materials: TSCA reporting and recordkeeping requirements.
https://www.govinfo.gov/content/pkg/FR-2017-01-12/pdf/2017-00052.pdf

b) a polymer that is not one of the types listed in Schedule 7 of the Regulations (see section 3.3.1.7) and that has a number average molecular weight greater than 1 000 daltons and equal to or less than 10 000 daltons, with less than 10% of its components having molecular weights less than 500 daltons and less than 25% of its components having molecular weights less than 1 000 daltons; or
c) a polymer that is a polyester manufactured solely from reactants listed in Schedule 8 of the Regulations (see Appendix 2) or an anhydrous form of those reactants, other than the reactants or their anhydrous forms that include both 1-butanol and fumaric or maleic acid.

Note that paragraph 9(c) does not reference Schedule 7 and does not include restrictions on molecular weight. A polymer meeting the criterion under this paragraph is considered RRR, irrespective of stability and molecular weight.

3.3.1.6 Non-Reduced Regulatory Requirement Polymers

Polymers that do not meet the criteria under section 9 of the Regulations are referred to as non-RRR polymers. Non-RRR polymers require additional notification requirements at higher manufacture or import quantities (see Table 1-1). Non-RRR polymers are added to the DSL once all criteria for addition are met (see section 4.9).

3.3.1.7 Polymers described in Schedule 7 of the Regulations

Schedule 7 of the Regulations outlines criteria used to determine whether a polymer is considered RRR under paragraphs 9(a) and (b) of the Regulations, based on the amounts of cationic groups, stability, elemental composition and amounts of reactive functional groups. Schedule 7 includes 5 items; items 1 to 4 apply under paragraph 9(a) and items 1 to 5 apply under paragraph 9(b). For the purpose of paragraphs 9(a) and 9(b) of the Regulations, a polymer described in Schedule 7 is considered non-RRR.

According to item 1, a polymer that is reasonably expected to become cationic in a natural aquatic environment is considered non-RRR. However, a polymer that is potentially cationic could be considered RRR if it meets the criterion under either paragraph 1(a) or (b). To determine the applicability of paragraph 1(a), the functional group equivalent weight (FGEW) of cationic groups must be calculated (see section 3.3.1.8). To determine the applicability of paragraph 1(b), no FGEW calculation is required.

Item 2 describes a polymer that is considered non-RRR based on stability (see section 3.3.1.9).

Items 3 and 4 describe a polymer that is considered non-RRR based on elemental composition.

Item 5 is only applicable under paragraph 9(b). It describes a polymer that is considered non-RRR based on combined FGEW of specific reactive functional groups:

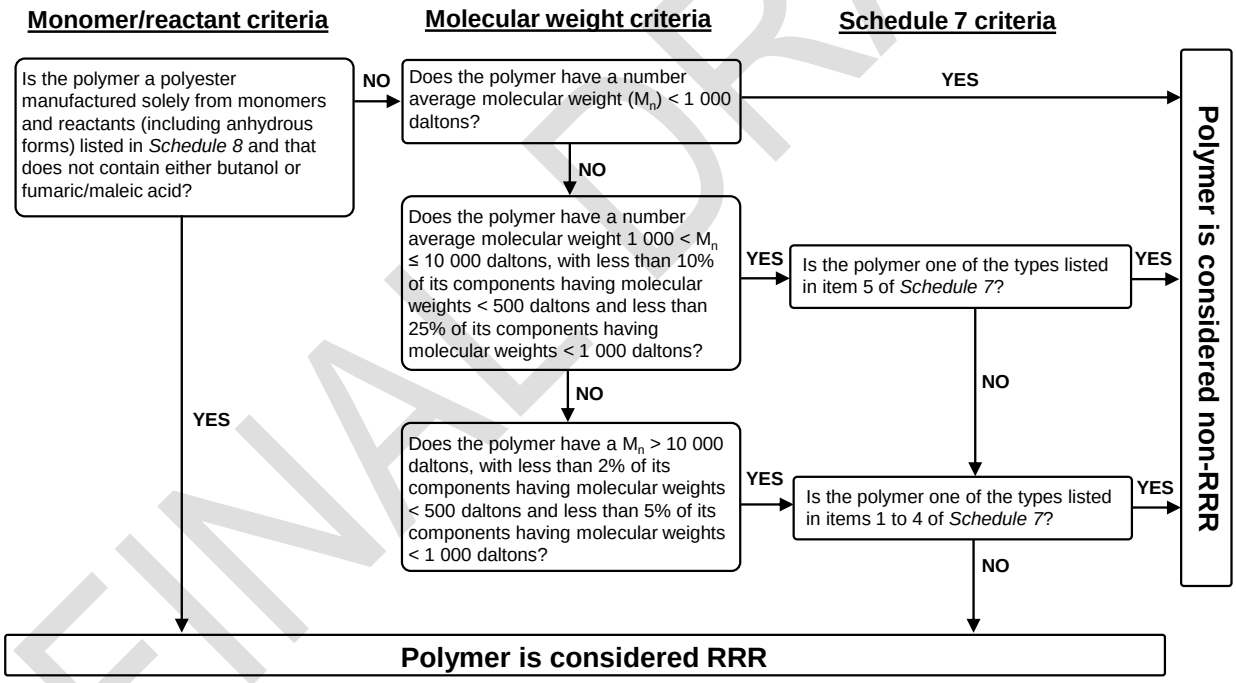
- A polymer that has a combined FGEW less than 5 000 daltons for reactive functional groups **other than those listed in paragraph 5(a)** is considered a non-RRR polymer; and
- A polymer that has a combined FGEW less than 1 000 daltons for **the functional groups listed in paragraph 5(b)** is also considered a non-RRR polymer.

The higher FGEW threshold in paragraph 5(a) indicates higher concerns associated with the functional groups referred to in this paragraph.

Methods for calculating the FGEW of cationic or reactive functional groups for different functional group distributions are presented in section 3.3.1.8.

Figure 3-1 below presents a decision tree for determining whether a polymer is considered an RRR polymer or a non-RRR polymer.

Figure 3-1 Reduced Regulatory Requirement Polymer Decision Tree



3.3.1.8 The Functional Group Equivalent Weight

The FGEW is the theoretical molecular weight of the polymer that contains one equivalent weight (one mole) of a particular functional group. There is an inverse relationship between the FGEW value for a particular functional group and the expected number of occurrences of that functional group in the polymer. For example, a FGEW of 700 daltons means there is on average one functional group in every 700 daltons of the polymer, while a FGEW of 4500 daltons means there is on average one functional

group in every 4500 daltons of the polymer. Consequently, a higher FGEW value is associated with a lower potential level of concern.

Functional groups can be distributed throughout the polymer or located in terminal positions. To calculate the FGEW for any reactive functional group of concern or cationic group, it is essential to know how the functional groups are distributed within the polymer, and in the case of terminal positioning, whether the polymer is linear or branched.

Equations to calculate the FGEW

Eq. #	Calculation description	Equation
1	FGEW of functional group distributed throughout the polymer	$FGEW_{FG} = \frac{mw_{mon} \cdot 100}{wt\%_{mon} \cdot nFG_{mon}}$
2	FGEW of functional group in end-group (=terminal) position, linear polymers	$FGEW_{FGEG\_LP} = \frac{Mn}{nEG \cdot nFG_{mon}}$
3	FGEW of functional group in end-group (=terminal) position, branched polymers	$FGEW_{FGEG\_BP} = \frac{Mn}{\left(\left(\frac{Mn \cdot wt\%_{BA}}{mw_{BA} \cdot 100}\right) \cdot (nRS - 2) + 2\right) \cdot nFG}$
4	Combined FGEW calculation	$FGEW_{comb.} = \frac{1}{{}^{1}/_{FGEW_1} + {}^{1}/_{FGEW_2} + \cdots {}^{1}/_{FGEW_n}}$
5	FGEW derived from amine number	$FGEW_{amine} = \frac{(mw\ of\ KOH)}{Amine\ number}$ $= \frac{56.1\ {}^{g}/_{mol}}{x_{amine}\ {}^{mg}/_{1\,000\ mg}} = \frac{56.1\ \cdot 1\,000}{x_{amine}} \frac{g}{mol}$
6	# moles of a functional group (# moles of functional group / 100 g polymer)	$moles_{FG} = \frac{wt\%_{mon} \cdot nFG}{mw_{mon}}$

Abbreviations		Indices	
FGEW	functional group equivalent weight (daltons)	$_{mon}$	monomer
wt%	weight percent	$_{BA}$	branching agent
nFG	number of available* functional groups	$_{FGEG}$	functional group in end group position
Mn	number average molecular weight (daltons)	$_{FGEG\_LP}$	FGEG linear polymer
mw	molecular weight (daltons)	$_{FGEG\_BP}$	FGEG branched polymer
nEG	number of end-groups	$_{comb.}$	combined
nRS	number of reactive sites	$FGEW_n$ $_{n=1,2,3....}$	individual FGEW calculations
x_{amine}	amine number, mg KOH/g polymer	$_{amine}$	cationic amine
mw KOH	molecular weight of KOH = 56.1 g/mol		

* "available" means functional groups that must be considered in the FGEW calculation

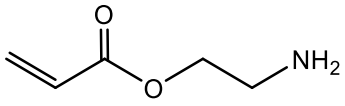
Equation 1 takes into account how much reactant is charged to the reactor and assumes that the reactants are completely incorporated into the polymer during the reaction. This equation should be used whenever the incorporation of the reactant would always result in its reactive functional groups being available: i.e. the availability of the reactive functional groups is not affected by the position of the reactant. This equation can also be used to check the results of other equations (see examples 1, 2 and 3).

Functional groups that are consumed and incorporated into the polymer backbone are not considered in the FGEW calculation. When a functional group is incorporated into the backbone but still appears in the terminal position of a polymer, the FGEW should be calculated using **equation 2 or 3**. If **equation 1** were used when the functional groups were only available in the terminal positions, the resulting FGEW would be artificially low and would overestimate the concern since this equation does not account for functional groups that become unavailable after being incorporated into the backbone of the polymer. **Equations 2 and 3** account for polymer reactants whose functional groups are consumed during polymerization and whose only remaining available functional groups are found at the terminal positions of linear or branched polymers, respectively. Note that this calculation assumes that all terminal positions are occupied by the reactant carrying the functional group of concern. Additional equations accounting for the molar ratios of the other functional groups of the polymer reactants and the order of addition can also improve accuracy of the FGEW calculation, however this exceeds the scope of the materials presented in this guidance.

Example 1

An acrylic polymer has a M_n of 2 745 daltons, 21 wt.% below 1 000 daltons and 7 wt.% below 500 daltons.

The acrylic backbone has randomly distributed pendant aliphatic amines derived solely from its content of 2% by weight 2-propenoic acid, 2-aminoethyl ester (CAS registry number 7659-38-3, $C_5H_9NO_2$, mw = 115 daltons).



$C_5H_9NO_2$, mw = 115 daltons

Note: the acrylic functional group of this reactant will react into the backbone of the polymer; only the cationic secondary amine needs to be considered.

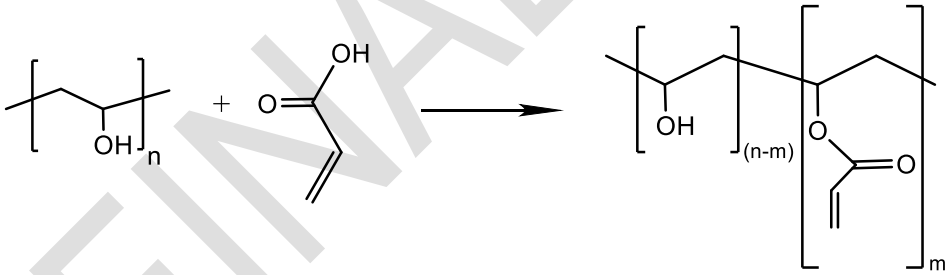
The $FGEW_{amine}$ is calculated using **equation 1:** FGEW of functional group distributed throughout the polymer.

$$FGEW_{FG} = \frac{mw_{mon} \cdot 100}{wt\%_{mon} \cdot nFG_{mon}} = \frac{115\ daltons\ \cdot 100}{2 \cdot 1} = 5\,750\ daltons$$

The polymer meets the exception criterion under paragraph 1(a) of Schedule 7 (the combined FGEW of cationic groups must be greater than 5 000 daltons), and therefore, this polymer is not one of the types listed in item 1 of Schedule 7.

Example 2

A reaction product of 2-propenoic acid (CAS registry number 79-10-7) and ethenol, homopolymer (CAS registry number 9002-89-5) has a M_n of 8 500 daltons, 17 wt.% below 1 000 daltons and 4.7 wt.% below 500 daltons.



The carboxylic acid group of 2-propenoic acid (mw = 72 daltons) reacts with the pendant alcohol groups of the pre-polymer; the resulting polymer therefore contains randomly distributed pendant acrylates.

Based on the description provided above (M_n and reactants), this polymer does not meet the definition of neither paragraph 9(a) nor (c) of the Regulations. According to paragraph 9(b), it must be determined whether the polymer is described in Schedule 7, including in item 5.

Pendant acrylates are reactive functional groups that are not listed in paragraph 5(a) of Schedule 7; correspondingly the FGEW threshold of 5 000 daltons applies to this functional group.

The polymer contains 5.5 wt.% of the reactant 2-propenoic acid, which has a molecular weight of 72 daltons.

The FGEW of the pendant acrylate functional group is also calculated according to **equation 1**:

$$FGEW_{FG} = \frac{mw_{mon} \cdot 100}{wt\%_{mon} \cdot nFG_{mon}} = \frac{72\ daltons \cdot 100}{5.5 \cdot 1} = 1\,309\ daltons$$

The FGEW for the pendant acrylate group is less than 5 000 daltons; the polymer is therefore described in paragraph 5(a) of Schedule 7. This polymer is considered non-RRR.

Note: A polymer with the same composition and meeting the M_n and oligomer content requirements of paragraph 9(a) would be considered RRR. A FGEW calculation would not be required.

Example 3

Note: The following example illustrates that even when the functional group of concern is located in terminal position only, calculating the FGEW via endgroup analysis might still be inappropriate.

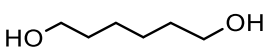
The example polymer has a M_n of 6 800 daltons, 7 wt.% of components of molecular weight below 1 000 daltons and 3 wt.% of components of molecular weight below 500 daltons.

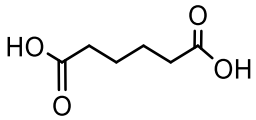
The polymer consists of 91.6 wt.% of a pre-polymer of hexanedioic acid, polymer with 1,6-hexanediol (CAS registry number 25212-06-0) that is reacted with 8.4 wt.% pentaerythritol triacrylate (CAS registry number 3524-68-3).

CAS registry number 25212-06-0 consists of

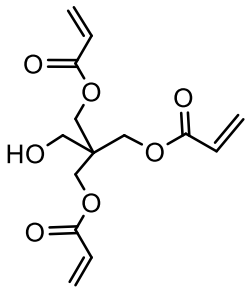
CAS registry number 629-11-8 and CAS registry number 124-04-9

Hexanediol, mw = 118 daltons Hexanedioic, mw = 146 daltons





CAS registry number 3524-68-3 Pentaerythritol triacrylate, mw = 298 daltons



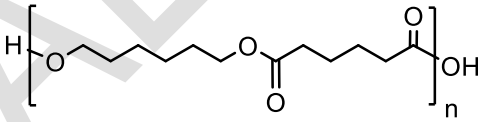
Pentaerythritol triacrylate can only react with the pre-polymer via its alcohol group; the three acrylate functional groups will remain pendant.

Based on the description provided above (M_n and reactants), this polymer does not meet the definition of neither paragraph 9(a) nor (c) of the Regulations. According to paragraph 9(b), it must be determined whether the polymer is described in Schedule 7, including in item 5.

Pendant acrylates are reactive functional groups that are not listed in paragraph 5(a) of Schedule 7; correspondingly the FGEW threshold of 5 000 daltons applies to this functional group.

The pre-polymer is linear and its only available functional groups are in terminal positions. The alcohol group of pentaerythritol triacrylate can only react with hexanedioic acid, i.e. with those end-positions that are terminated by hexanedioic acid.

If equal molar amounts of hexanedioic acid and 1,6-hexanediol are reacted, the end-positions of the resulting polymer will ideally be equally terminated by acid and alcohol groups.



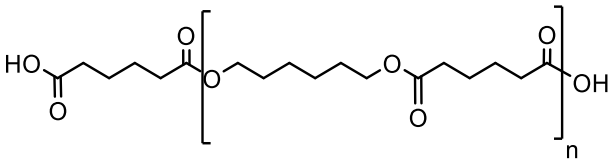
This would be the case, if the polymer consisted of 55.3 wt.% hexanedioic acid and 44.7 wt.% of 1,6-hexanediol, thus reacting equal molar amounts of each reactant. For the comparison of molar amounts/100g , **equation 6** is used:

$$moles_{FG(OH)} = \frac{44.7 \cdot 1}{118\ daltons} = 0.3788$$

$$moles_{FG(COOH)} = \frac{55.3 \cdot 1}{146\ daltons} = 0.3788$$

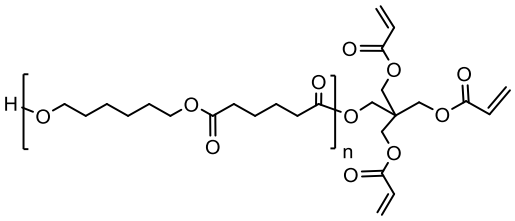
In case of sufficient excess[14] of hexanedioic acid, the resulting polymer will only contain terminal acid groups.

[14] "Sufficient excess" is a complex calculation that depends on the M_n of the intended polymer

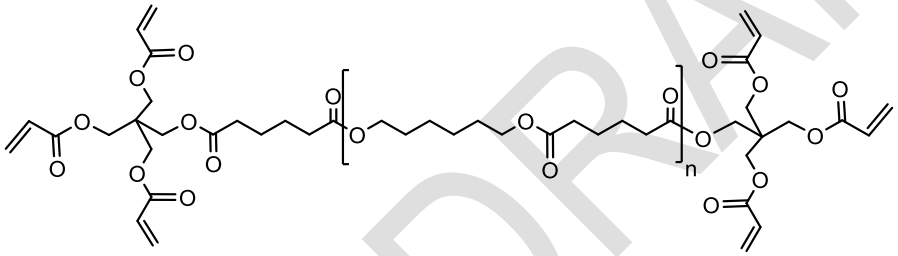


Whether hexanedioic acid is present in one or both end-positions will determine whether pentaerythritol triacrylate can react with one (A) or both (B) end-positions.

(A)



(B)



The $FGEW_{acrylate}$ could therefore be calculated using **equation 2**: FGEW of functional group in end-group (=terminal) position, linear polymers.

$$FGEW_{FGEG} = \frac{Mn}{nEG \cdot nFG_{mon}}$$

For (A), the calculation would be

$$FGEW_{FGEG} = \frac{Mn}{nEG \cdot nFG_{mon}} = \frac{6\,800\ daltons}{1 \cdot 3} = 2\,400\ daltons$$

For (B), the calculation would be

$$FGEW_{FGEG} = \frac{Mn}{nEG \cdot nFG_{mon}} = \frac{6\,800\ daltons}{2 \cdot 3} = 1\,200\ daltons$$

Neither of these two polymers (A) or (B) would therefore be considered RRR, as the polymer would be considered as one of the polymer types described in paragraph 5(a).

Important

This calculation assumes that the final polymer is intended to have as many terminal acrylate groups as supported by the composition of the pre-polymer, i.e. enough pentaerythritol triacrylate is added to cover all available end-positions.

To double-check that this is indeed the case, **equation 1** has to be used, as this equation takes the amount of reactant into consideration.

$$FGEW_{acrylate} = \frac{298\ daltons \cdot 100}{8.4 \cdot 3} = 1\ 183\ daltons$$

Calculating the FGEW via this equation would have provided the answer to whether the polymer is considered RRR or not immediately.

Considering the elaborate calculations above, the $FGEW_{acrylate}$ calculated based on this equation indicates that sufficient acrylate is charged to have all available end-groups of case (B) covered by this reactant. If the polymer was actually version (A), charging this amount of acrylate would be in excess (often noticeable as low molecular weight peak of unreacted monomer in the Gas Permeation Chromatography (GPC).

Example 4

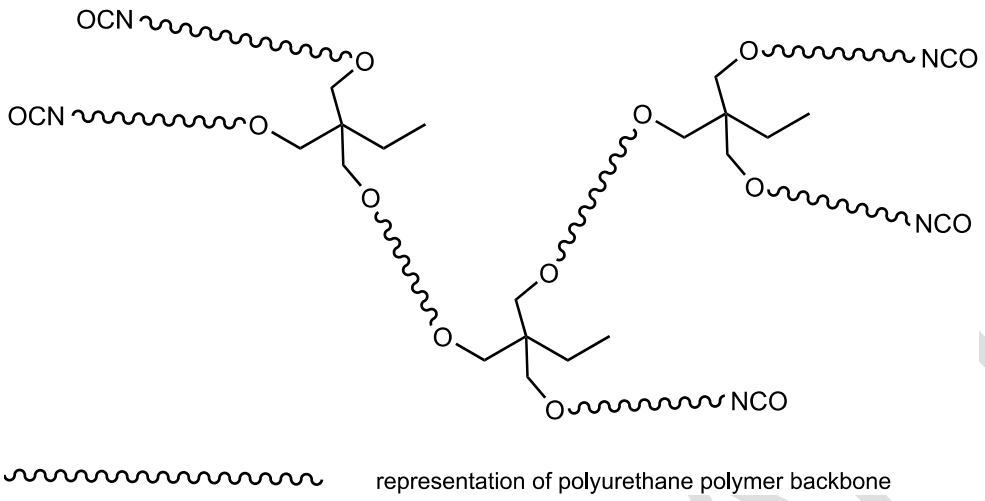
A linear polyurethane polymer has a M_n of 100 000 daltons and 0% of components of molecular weight below 1 000 daltons. Its isocyanate-containing reactant is aliphatic and therefore considered cationic after hydrolysis. Since the functional group reacts into urethane bonds within the polymer chain and hydrolyzes to a cationic amine in terminal position only, the FGEW has to be assessed via the analysis of available endgroups. Assuming all terminal positions of the polymer are occupied by aliphatic isocyanate groups, the $FGEW_{FGEG}$ is therefore calculated according to **equation 2**:

$$FGEW_{FGEG\_LP} = \frac{Mn}{2 \cdot nFG_{mon}} = \frac{100\ 000\ daltons}{2 \cdot 1} = 50\ 000\ daltons$$

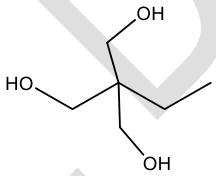
The FGEW for the cationic amine (i.e. after hydrolysis of the aliphatic isocyanate) is greater than the FGEW threshold for cationic groups of 5 000 daltons; therefore this polymer meets the exception criterion under paragraph 1(a) of Schedule 7. This polymer is not one of the types listed in item 1 of Schedule 7.

Note: An aromatic isocyanate would not have required calculation since aromatic isocyanates do not become cationic and the polymer would have met the requirements under paragraph 9(a), for which Schedule 7 item 5 does not apply.

Example 5



A branched polyurethane polymer of 9 600 daltons contains isocyanate groups at chain ends from an aromatic diisocyanate. The branching agent 1,3-propanediol, 2-ethyl-2-(hydroxymethyl) (CAS registry number 77-99-6) has a molecular weight of 134 daltons and accounts for 1 wt.% of the polymer; it has three reactive sites.

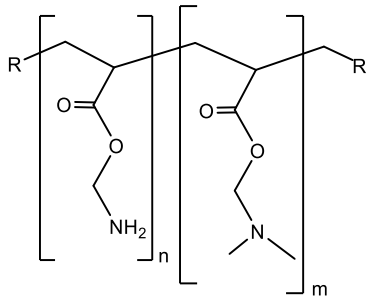


The FGEW for the functional group in end group position of a branched polymer has to be calculated according to **equation 3**:

$$FGEW_{FGEG\_BP} = \frac{Mn}{\left(\left(\frac{Mn \cdot wt\%_{BA}}{mw_{BA} \cdot 100}\right) \cdot (nRS - 2) + 2\right) \cdot nFG} = \frac{9\,600\ daltons}{\left(\left(\frac{9\,600\ daltons \cdot 1}{134\ daltons \cdot 100}\right)(3 - 2) + 2\right) \cdot 1} = 3\,534\ daltons$$

With a FGEW for the isocyanates of 3 534, the polymer is described by paragraph 5(a) of Schedule 7 and therefore is not considered RRR.

Example 6



An acrylic polymer contains aliphatic amines from 1 wt.% of 2-propenoic acid, 2-aminoethyl ester (CAS registry number 7659-38-3, molecular weight = 115 daltons) and 2 wt.% of (dimethylamino)ethyl methacrylate (CAS registry number 2867-47-2, molecular weight = 157 daltons). The FGEW for each of the cationic groups is calculated using **equation 1**:

$$FGEW_1 = \frac{mw_{mon} \cdot 100}{wt\%_{mon} \cdot nFG_{mon}} = \frac{115\ daltons \cdot 100}{1 \cdot 1} = 11\,500\ daltons$$

$$FGEW_2 = \frac{mw_{mon} \cdot 100}{wt\%_{mon} \cdot nFG_{mon}} = \frac{157\ daltons \cdot 100}{2 \cdot 1} = 7\,850\ daltons$$

The combined FGEW is then calculated using **equation 4**:

$$FGEW_{comb.} = \frac{1}{{}^{1}/_{FGEW_1} + {}^{1}/_{FGEW_2}} = \frac{1}{{}^{1}/_{11{,}500\ daltons} + {}^{1}/_{7{,}850\ daltons}} = 4{,}665\ daltons$$

With a combined FGEW for cationic groups of less than 5 000 daltons the polymer is described by item 1 of Schedule 7 and is therefore not considered RRR.

Example 7

For many complex polymers (e.g. polymers containing pre-polymers), it is impossible to calculate the FGEW for a specific functional group of concern without requiring additional information; for example, the pre-polymer's composition or M_n or both.
In the case of cationic functional groups, an empirically determined amine number provides the most accurate information on the actual cationic charge present. For example for an amine number of 7.5 mg KOH/g polymer, the calculation according to **equation 5** would be:

$$FGEW = \frac{(mw\ of\ KOH)}{Amine\ number} = \frac{56.1\ \times 1000}{7.5}\frac{g}{mol} = 7\,480\ daltons$$

Turning this equation around, any amine number above 11.22 indicates that the polymer is mentioned under item 1 of Schedule 7 and therefore is considered non-RRR:

$$5{,}000 < \frac{56.1 \times 1000}{x} \rightarrow x < \frac{56\,100}{5\,000} \rightarrow x < 11.22$$

3.3.1.9 Polymers that Substantially Degrade, Decompose or Depolymerize

One of the criteria in determining whether a polymer qualify as an RRR polymer is whether it is designed or expected to “substantially degrade, decompose or depolymerize.” This criterion is set out in Schedule 7, item 2 of the Regulations. If the substance meets this or other criteria set out in Schedule 7, it would not qualify as an RRR polymer.

In interpreting this criterion, the NS program will consider both the extent of degradation, decomposition or depolymerization and the hazard of the transformation products.

- If the transformation products of a polymer are of low hazard, it may qualify as an RRR polymer, despite degrading, decomposing or depolymerizing, depending on whether other criteria are met.

When a notifier claims that a polymer is to be considered RRR, he or she should provide information to support the assessment of whether the polymer is substantially degradable. In the absence of such information, the NS program will use its best judgement in making the determination. To support the claim, notifiers should provide information about whether the polymer is degradable, including whether the polymer is a member of a class of polymers known to be readily transformed (e.g., polysaccharides or certain bio-based polyesters). In cases where it is anticipated that the polymer will degrade, or where there is empirical evidence that it will degrade, the notifier should identify the known or anticipated transformation products and provide information concerning their hazard so that the program can assess the RRR claim.

Since experimental information may not be available, predictive programs may be used to address the stability of the polymer, the formation of stable transformation products and their hazard characteristics. Other methods such as obtaining data from the literature or using “read-across” techniques may be acceptable.

As with all information and claims provided in a notification, the NS program will assess their merits in determining whether this criterion is met.

3.4 Special Category Substances

A special category substance is defined as any substance that is manufactured or imported as

a) a research and development substance;
b) a contained site-limited intermediate substance; or
c) a contained export-only substance.

3.4.1 Research and Development Substances

Subsection 1(1) of the Regulations defines a research and development substance as one that is undergoing systematic investigation or research, by means of

experimentation or analysis other than test marketing, whose primary objective is any of the following:

a) to create or improve a product or process;
b) to determine the technical viability or performance characteristics of a product or process; or
c) to evaluate a substance prior to its commercialization, by pilot plant trials, production trials (including scale-up) or customer plant trials, so that technical specifications can be modified in response to the performance requirements of potential customers.

This category includes chemicals or polymers being manufactured on toll for domestic or foreign customers that are conducting research (see section 1.4.3).

The Regulations also define “Test marketing,” in respect of a product as referred to above, as “the exploration of its market capability in a competitive situation where the creation or improvement of the product is not the primary objective.”

3.4.2 Contained Site-Limited Intermediates

Subsection 1(1) of the Regulations defines a site-limited intermediate as a substance that is consumed in a chemical reaction used for the manufacture of another substance and that is

a) manufactured and consumed at the site of manufacture;
b) manufactured at one site and transported to a second site where it is consumed; or
c) imported and transported directly to the site where it is consumed.

The Regulations also define

- “contained” as “an absolute release limit of 1 kg per day per site of the substance to the aquatic environment after wastewater treatment”; and
- “consumed” as “destroyed or completely converted to another substance.”

If a substance is classified as a site-limited intermediate, it must, at all times during its existence (manufacture, importation, storage, transport, handling, use and disposal), be contained, as defined above, to prevent any significant environmental release.

A substance that is a direct precursor in the manufacture of an item defined in section 3.2.2 is not considered a site-limited intermediate and would be subject to the notification requirements. However, if the direct precursor of the item meets the criteria of a “transient reaction intermediate” (see section 3.2.5), it would not be subject to notification.

3.4.3 Contained Export-Only Substances

Contained export-only substances are limited to new substances manufactured in or imported into Canada that are destined solely for foreign markets and that are contained.

“Contained” is defined in subsection 1(1) of the Regulations as an absolute release limit of 1 kg/day per site of the substance to the aquatic environment after wastewater treatment.

SECTION 4 — NOTIFICATION INFORMATION REQUIREMENTS

4.1 How to Identify the Required Notification Information

The *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) prescribe information requirements tailored to the use and quantity of the chemical or polymer being manufactured or imported. These requirements are listed in the Schedules of the Regulations, which are presented in Appendix 2 of this Guidance Document. To help select the appropriate Schedule, decision flowcharts are provided in this section and also in Appendix 1.

It is important to note that although the Regulations provide a tiered approach to notification, which links information requirements to factors such as quantity, use, intrinsic properties and class, it is not a requirement to follow this tiered notification approach. A notifier may, if he or she wishes, opt to immediately submit the highest notification Schedule required, as long as the lowest prescribed quantities for the lowest Schedule are not exceeded and the New Substances Notification (NSN) is submitted within the timeframe prescribed for the highest Schedule.

As indicated in the decision diagram presented below and in Appendix 1, there are a number of factors that must be considered when identifying the nature of the information to be submitted and when it should be submitted. These factors include

a) whether the new substance is a chemical or a polymer (see section 3.3);
b) whether the new substance falls within any of the prescribed special categories (i.e., research and development, contained site-limited intermediate or contained export-only; see section 3.4);
c) whether the new substance is listed on the Non-domestic Substances List (NDSL) (see section 2.2);
d) the annual quantities of the new substance that will be manufactured in or imported into Canada (see Table 1-1 and sections 4.2, 4.4, 4.5, 4.8 and 4.9);
e) if the new substance is a polymer, whether it meets the definition of a Reduced Regulatory Requirement (RRR) polymer (see section 3.3.1.5);
f) if the new substance is a polymer, whether it is manufactured solely from monomers and reactants that are listed on the Domestic Substances List (DSL) or the NDSL (see section 4.7.1); and
g) whether the new substance will have high release or significant public exposure (see sections 4.4.3 and 4.9.2).

4.1.1 Annual Quantities

The Regulations prescribe a pre-manufacture/pre-import notification scheme. As such, the notifier must develop an accurate estimate of the annual (calendar year) quantities of the new substance to be manufactured in or imported into Canada and submit an NSN before each of the prescribed quantities is exceeded.

The prescribed quantities relate to the actual amount of new substance manufactured or imported, not to the quantity of the formulation containing the substance. For example, if 10 000 kg of Formulation A are to be imported during a calendar year and this formulation contains 13% of new substance X, then the annual import quantity of substance X would be 1 300 kg.

The following sections will help identify both the Schedule requirements necessary to comply with the Regulations and the date before which NSNs must be submitted to the New Substances (NS) program.

4.2 Notification of Special Category Substances

Substances being manufactured or imported solely for activities defined under the special categories umbrella (see section 3.4) must be notified as indicated below. If any amount of the substance is to be used for an activity not within the special category umbrella, the substance is subject to notification under the appropriate Schedules based on the quantity to be used in the non-special category activity (see sections 4.3 and 4.7). These requirements are specified in the Schedules in Appendix 2 of this Guidance Document.

4.2.1 Lower-Quantity Special Category Notifications for Chemicals (See Figure 4-1)

Every notifier who manufactures or imports a chemical for research and development purposes, as a contained site-limited intermediate substance or as a contained export-only substance, must provide the Minister of the Environment (the Minister) with the information prescribed in Schedule 1 of the Regulations at least 30 days prior to the day on which the quantity of substance manufactured or imported exceeds 1 000 kg in a calendar year.

4.2.1.1 Lower-Quantity Research and Development Biochemicals

If the substance is a research and development biochemical, the notifier is required to provide, in addition to the Schedule 1 information noted above, the information specified in items 1 and 2 of Schedule 2 of the Regulations.

4.2.1.2 Lower-Quantity Contained Site-Limited Intermediate Biochemicals

If the substance is a contained site-limited intermediate biochemical that is not manufactured and consumed at the site of manufacture, the notifier is required to provide, in addition to the Schedule 1 information noted above, the information specified in items 1–4 of Schedule 2 of the Regulations and,

a) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations; and

b) if the biochemical possesses enzymatic capability, the information specified in items 7–13 of Schedule 2 of the Regulations.

If the substance is a contained site-limited intermediate biochemical that is manufactured and consumed at the site of manufacture, the notifier is required to provide, in addition to the Schedule 1 information noted above, the information specified in items 1, 2 and 4 of Schedule 2 of the Regulations.

4.2.1.3 Lower-Quantity Contained Export-Only Biochemicals

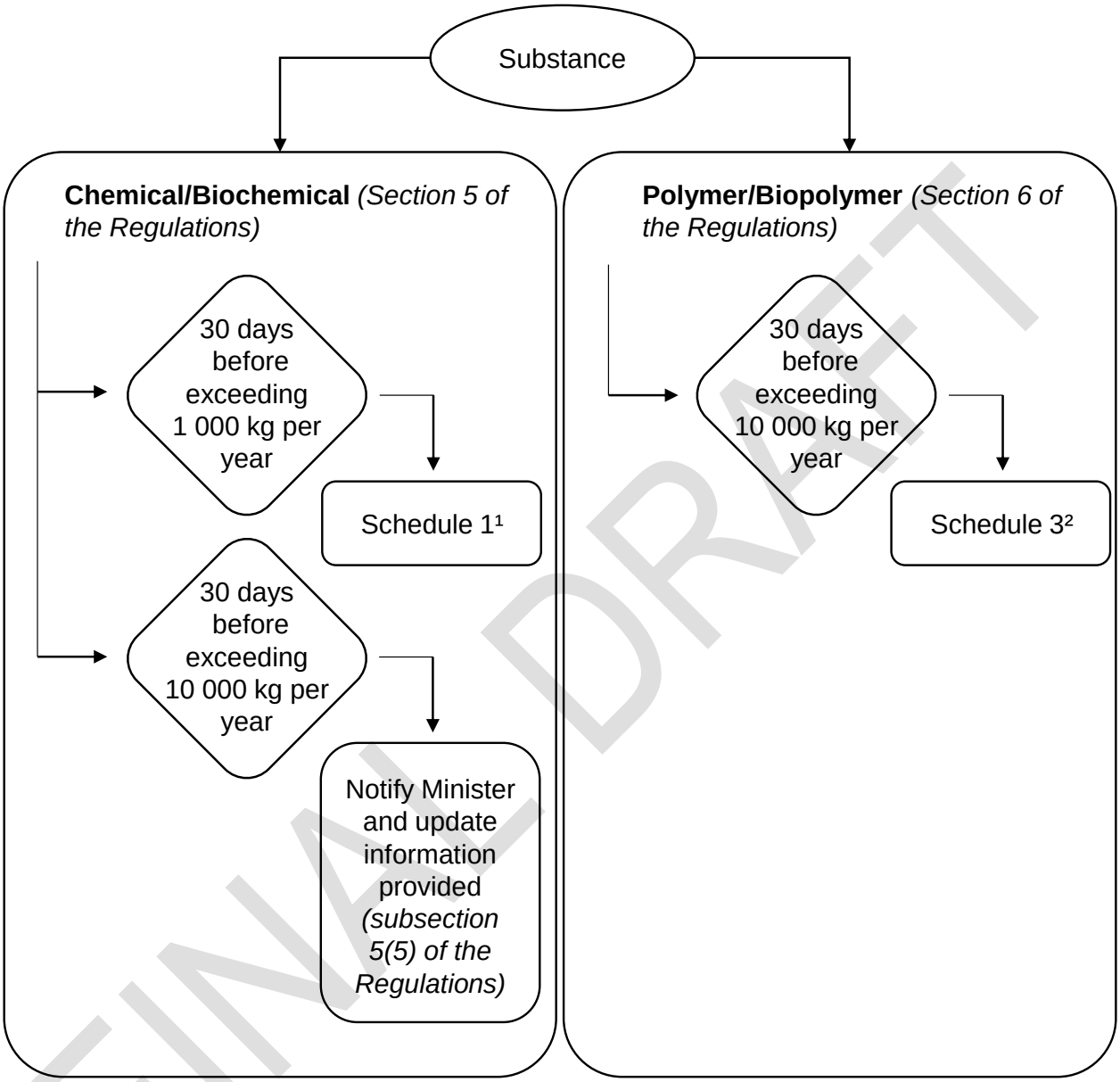
If the substance is a contained export-only biochemical, the notifier is required to provide, in addition to the Schedule 1 information noted above, the information specified in items 1–4 of Schedule 2 of the Regulations and,

a) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations; and
b) if the biochemical possesses enzymatic capability, the information specified in items 7–13 of Schedule 2 of the Regulations.

4.2.2 Higher-Quantity Special Category Notifications for Chemicals (See Figure 4-1)

In addition, the notifier must update all of the information that was previously provided at least 30 days prior to the day on which the quantity of substance manufactured or imported exceeds 10 000 kg in a calendar year. If there is no change in the information, that must be indicated at this time.

Figure 4-1 Research and Development, Contained Site-Limited Intermediate or Contained Export-Only Substances



[1] Additional information specified in Schedule 2 is also required if the chemical is a biochemical *(see subsections 5(2), (3) and (4) of the Regulations)*.

[2] Additional information specified in Schedule 2 is also required if the polymer is a biopolymer *(see subsections 6(2), (3) and (4) of the Regulations)*.

4.2.3 Higher-Quantity Special Category Notifications for Polymers (see Figure 4-1)

Every notifier who manufactures or imports a polymer for research and development purposes, as a contained site-limited intermediate polymer or as a contained export-only polymer must provide the Minister with the information prescribed in Schedule 3 of the Regulations at least 30 days prior to the day on which the quantity of substance manufactured or imported exceeds 10 000 kg in a calendar year.

4.2.3.1 Higher-Quantity Research and Development Biopolymers

If the substance is a research and development biopolymer, the notifier is required to provide, in addition to the Schedule 3 information noted above, the information specified in items 1 and 2 of Schedule 2 of the Regulations.

4.2.3.2 Higher-Quantity Contained Site-Limited Intermediate Biopolymers

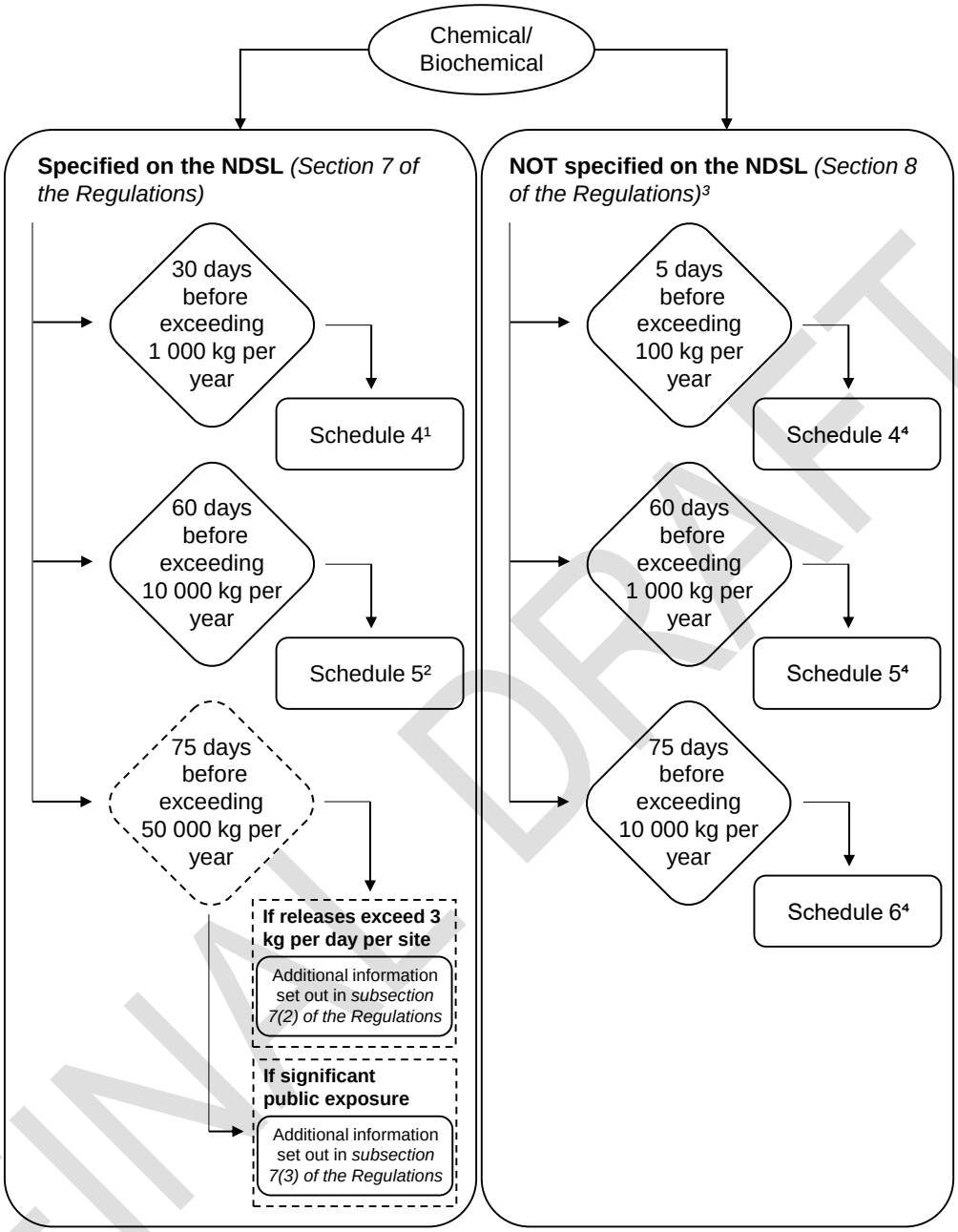
If the substance is a contained site-limited intermediate biopolymer that is not manufactured and consumed at the site of manufacture, the notifier is required to provide, in addition to the Schedule 3 information noted above, the information specified in items 1–4 of Schedule 2 of the Regulations and, if the biopolymer is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations.

If the substance is a contained site-limited intermediate biopolymer that is manufactured and consumed at the site of manufacture, the notifier is required to provide, in addition to the Schedule 3 information noted above, the information specified in items 1, 2 and 4 of Schedule 2 of the Regulations.

4.2.3.3 Higher-Quantity Contained Export-Only Biopolymers

If the substance is a contained export-only biopolymer, the notifier is required to provide, in addition to the Schedule 3 information noted above, the information specified in items 1–4 of Schedule 2 of the Regulations and, if the biopolymer is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations.

Figure 4-2 Chemical / Biochemicals Other Than Those In Figure 4-1



[1] Additional information specified in Schedule 2 is also required if the chemical is a biochemical *(see subparagraph 7(1)(a)(ii) of the Regulations)*.

[2] Additional information specified in Schedule 2 is also required if the chemical is a biochemical *(see subparagraph 7(1)(b)(ii) of the Regulations)*. No further information will be required unless: (a) the chemical is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment *(see subsection 7(2) of the Regulations)* or (b) the public may be significantly exposed to the chemical in a product *(see subsection 7(3) of the Regulations)*.

[3] Notification must be sent to the Minister if: the chemical or biochemical is specified on the NDSL following submission of the information to in *subparagraph 8(1)(b)(i) of the Regulations* and item 10 of Schedule 5 *(see subsection 8(2) of the Regulations)*.

[4] Additional information specified in Schedule 2 is also required if the chemical is a biochemical *(see subparagraphs 8(1)(a)(ii), b(ii) and c(ii) of the Regulations)*.

4.3 Notification of Chemicals

As indicated in section 4.1, the Regulations prescribe information requirements tailored to the use and quantity of the chemical. These requirements are specified in the Schedules in Appendix 2 of this Guidance Document. A decision flowchart is provided below and in Appendix 1 of this Guidance Document to assist in the selection of the appropriate notification Schedule.

Before using the flowchart, Table 1-1 and sections 2.2, 3.3, 3.4, 4.2.1, 4.2.2, 4.4 and 4.5 of this Guidance Document should be reviewed to determine

a) whether the new substance meets the definition of a chemical given in the Regulations (see section 3.3.1.1);
b) whether the new chemical falls within any of the prescribed special categories (i.e., research and development, contained site-limited intermediate or contained export-only; see section 3.4);
c) whether the new chemical is listed on the NDSL (see section 2.2);
d) the annual quantities of the new chemical that will be manufactured in or imported into Canada (see Table 1-1 and sections 4.2 to 4.5); and
e) whether the NDSL-listed chemical will have high release or significant public exposure (see section 4.4.3).

The following sections apply only to chemicals that are manufactured or imported for a purpose other than as a special category listed in section 3.4 of this Guidance Document.

4.4 Information Requirements for Chemicals Listed on the Non-domestic Substances List (see Figure 4-2)

4.4.1 Lower-Quantity Chemicals

Every notifier who manufactures or imports a chemical that is listed on the NDSL must provide the Minister with the information prescribed in Schedule 4 of the Regulations at least 30 days prior to the day on which the quantity of substance manufactured or imported exceeds 1 000 kg in a calendar year.

If the substance is a biochemical, the notifier is required to provide, in addition to the Schedule 4 information, the information specified in items 1–3 of Schedule 2 of the Regulations.

4.4.2 Higher-Quantity Chemicals

Every notifier who manufactures or imports a chemical that is listed on the NDSL must provide the Minister with the information prescribed in Schedule 5 of the Regulations at least 60 days prior to the day on which the quantity of substance manufactured or imported exceeds 10 000 kg in a calendar year.

If the substance is a biochemical, the notifier is required to provide, in addition to the Schedule 5 information, the information specified in items 1–4 of Schedule 2 of the Regulations and,

a) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations; and
b) if the biochemical possesses enzymatic capability, the information specified in items 7–13 of Schedule 2 of the Regulations.

4.4.3 Chemicals on the Non-domestic Substances List with High Release and/or Significant Public Exposure

Every notifier who manufactures or imports a chemical that is listed on the NDSL and

a) that is released to the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment; and/or
b) where the public may be significantly exposed to the chemical in a product

must provide the Minister with additional test information as prescribed in subsections 7(2) and/or 7(3) of the Regulations, respectively, at least 75 days prior to the day on which the quantity of substance manufactured or imported exceeds 50 000 kg in a calendar year. The additional required information is indicated in the following sections.

4.4.3.1 Chemicals Released to the Aquatic Environment

It is the notifier's responsibility to submit evidence in paragraph 10(*c*) of the Schedule 5 NSN to support a claim of the substance not being released to the aquatic environment in the quantity indicated above. This information should include any envisioned future use and quantity by other customers and a description of other envisioned applications. To calculate daily release to the aquatic environment, refer to section 6.6.5 of this Guidance Document.

The NS program will assess this information and if it is determined that the substance is released to the aquatic environment in quantities greater than indicated above, the additional information prescribed in subsection 7(2) of the Regulations must be provided. The NS program's determination of whether the substance is subject to additional information requirements given below will be provided to the notifier. The notifier may submit additional information to support his or her claim and request a re-evaluation of the decision made by the NS program by contacting the Substances Management Information Line. The NS program will review and consider the information submitted.

The additional information required, as prescribed in subsection 7(2) of the Regulations, must include the following:

a) for chemicals having a water solubility of greater than or equal to 200 µg/L:
   i) adsorption–desorption screening test data; and
   ii) the hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis; and
b) the data from a repeated-dose mammalian toxicity test of the chemical of at least 28 days' duration, using the most significant route of potential public exposure to the chemical, namely, oral, dermal or inhalation, in addition to
   i) the age, sex, number, species, strain and source of the animals tested;
   ii) the route by which the chemical is administered and the conditions under which the test is conducted; and
   iii) the dose of the chemical, the vehicle by means of which the chemical is administered and its concentration in that vehicle.

4.4.3.2 Where the Public May Be Significantly Exposed to the Chemical in a Product

It is the notifier's responsibility to submit information in paragraph 10(d) of the Schedule 5 NSN to support a claim of the public not being significantly exposed to the substance in a product. The NS program's determination of whether the substance is subject to the additional information requirements given below will be provided to the notifier. The notifier may submit additional information to support his or her claim and request a re-evaluation of the decision made by the NS program by contacting the Substances Management Information Line. The NS program will review and consider the information submitted.

Since public exposure is dependent on many factors, a single calculation to determine "significant exposure" cannot be applicable to all circumstances without being extremely conservative. Therefore, the definition of "significantly exposed" will be assessed, by the NS program, on a case-by-case basis. This information should take into consideration such factors as type of use, duration and frequency of use, concentration of the chemical in the product and circumstances of exposure that may limit direct public exposure (e.g., whether the chemical is consumed during use or is able to migrate from the product). To determine whether the public may be significantly exposed to the chemical in a product, the NS program provides the opportunity for notifiers to submit a Pre-notification Consultation (PNC) request (see section 8.8).

Some examples of consumer applications where significant public exposure of a substance may occur include, but are not limited to, dishwashing detergent, laundry products, soaps, toilet paper, cleaning solutions, waxes, polishes, air fresheners, paints, oils, greases, body lotions, and ink.

If it is determined that the public may be significantly exposed to the chemical in a product, the additional information prescribed in subsection 7(3) of the Regulations must be provided. The additional information required, as prescribed in subsection 7(3) of the Regulations, must include the following:

a) the data from a repeated-dose mammalian toxicity test of the chemical of at least 28 days' duration, using the most significant route of potential public exposure to the chemical, namely, oral, dermal or inhalation, in addition to
   i) the age, sex, number, species, strain and source of the animals tested;
   ii) the route by which the chemical is administered and the conditions under which the test is conducted; and
   iii) the dose of the chemical, the vehicle by means of which the chemical is administered and its concentration in that vehicle; and
b) the data obtained from an *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells or the data from a previously existing *in vivo* mammalian test for chromosomal aberrations that, together with data substantiating that the tissue investigated was exposed to the chemical or its metabolites, permits an assessment of *in vivo* clastogenicity.

4.5 Information Requirements for Chemicals Not on the Non-domestic Substances List (See Figure 4-2)

4.5.1 Lower-Quantity Chemicals

a) Every notifier who manufactures or imports a chemical that is not on the NDSL must provide the Minister with the information prescribed in Schedule 4 of the Regulations at least five days prior to the day on which the quantity of substance manufactured or imported exceeds 100 kg in a calendar year.

   If the substance is a biochemical, the notifier is required to provide, in addition to the Schedule 4 information, the information specified in items 1–3 of Schedule 2 of the Regulations.

b) Every notifier who manufactures or imports a chemical that is not on the NDSL must provide the Minister with the information prescribed in Schedule 5 of the Regulations at least 60 days prior to the day on which the quantity of substance manufactured or imported exceeds 1 000 kg in a calendar year.

   If the substance is a biochemical, the notifier is required to provide, in addition to the Schedule 5 information, the information specified in items 1–4 of Schedule 2 of the Regulations and,

   i) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations; and
   ii) if the biochemical possesses enzymatic capability, the information specified in items 7–13 of Schedule 2 of the Regulations.

4.5.2 Higher-Quantity Chemicals

Every notifier who manufactures or imports a chemical that is not on the NDSL must provide the Minister with the information prescribed in Schedule 6 of the Regulations at

least 75 days prior to the day on which the quantity of substance manufactured or imported exceeds 10 000 kg in a calendar year.

If the substance is a biochemical, the notifier is required to provide, in addition to the Schedule 6 information, the information specified in items 1–4 of Schedule 2 of the Regulations and,

a) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations; and
b) if the biochemical possesses enzymatic capability, the information specified in items 7–13 of Schedule 2 of the Regulations.

4.6 Information Requirements for Chemicals that are Subsequently Added to the Non-domestic Substances List

It is important to note that, should a chemical be added to the NDSL after a complete Schedule 4 and 5 NSN has been submitted (including item 10 of Schedule 5 of the Regulations), the notifier may, as per subsection 8(2) of the Regulations, advise the NS program, in writing, that the information is to be considered as having been submitted under paragraph 7(1)(*b*) of the Regulations. Once the appropriate fee has been submitted (see fee table on the NSN fees webpage[15]), a 60-day assessment period will commence, to re-assess the substance as a final NSN.

In addition, once a substance is added to the NDSL, it may require the additional data prescribed in subsection 7(2) or 7(3) of the Regulations to be submitted if the substance has high release or significant public exposure (see section 4.4.3).

4.7 Notification of Polymers

Similar to the notification of chemicals and biochemicals, the Regulations prescribe information requirements tailored to the use and quantity of the polymer. These requirements are specified in the Schedules in Appendix 2 of this Guidance Document. A decision flowchart is provided below and in Appendix 1 of this Guidance Document to assist in selection of the appropriate notification Schedule.

Before using the flowchart, Table 1-1 and sections 2.2, 3.3, 3.4, 4.2.3, and 4.7 through 4.9 of this Guidance Document should be reviewed to determine

a) whether the new substance meets the definition of a polymer given in the Regulations (see section 3.3.1.2);
b) whether the new polymer falls within any of the prescribed special categories (i.e., research and development, contained site-limited intermediate or contained export-only; see section 3.4);
c) whether the new polymer is listed on the NDSL (see section 2.2);

[15] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

d) the annual quantities of the new polymer that will be manufactured in or imported into Canada (see Table 1-1 and sections 4.2.3, 4.8 and 4.9);
e) whether the new polymer meets the definition of an RRR polymer (see section 3.3.1.5);
f) whether the new polymer is manufactured solely from monomers and reactants that are listed on the DSL or NDSL (see section 4.7.1); and
g) whether the NDSL-listed polymer or the polymer manufactured solely from monomers and reactants that are listed on the DSL or NDSL will have high release or significant public exposure (see section 4.9.2).

The following sections apply only to polymers that are manufactured or imported for a purpose other than as a special category listed in section 3.4 of this Guidance Document.

4.7.1 Monomers and Reactants Listed on the Domestic Substances List or the Non-domestic Substances List

To determine whether a Non-reduced Regulatory Requirement polymer (non-RRR) notification can be considered under a schedule with fewer information requirements, i.e., under schedule 10 instead of schedule 11 for a 10 000 kg trigger quantity, it is necessary to find out whether the monomers and reactants of the substance are listed on the DSL or NDSL.

To determine the presence of monomers and reactants confidentially or publicly listed on the DSL and NDSL, the Chemical Abstracts Service Registry Number can be searched in the search engine located on the NS program website at https://pollution-waste.canada.ca/substances-search/Substance?lang=en.

Alternatively, a Notice of *Bona Fide* Intent to Manufacture or Import can be sent to the NS program (see section 2.3.1).

4.8 Information Requirements for Polymers (See Figure 4-3)

4.8.1 Reduced Regulatory Requirement Polymers and Lower-Quantity Non-Reduced Regulatory Requirement Polymers

Every notifier who manufactures or imports any polymer must provide the Minister with the information prescribed in Schedule 9 of the Regulations at least 30 days prior to the day on which the quantity of substance manufactured or imported exceeds 1 000 kg in a calendar year. If the substance is considered an RRR polymer (see section 3.3.1.5), the Schedule 9 NSN is the final notification requirement.

If the substance is a biopolymer, the notifier is required to provide, in addition to the Schedule 9 information, the information specified in items 1–3 of Schedule 2 of the Regulations.

4.9 Information Requirements for Non-Reduced Regulatory Requirement Polymers (See Figure 4-3)

The sections 4.9.1 to 4.9.3 do not apply to polymers that meet the RRR polymer criteria.

4.9.1 Higher-Quantity Non-RRR Polymers Either on the NDSL or Manufactured from Reactants on the DSL or NDSL

Every notifier who manufactures or imports a non-RRR polymer (see section 3.3.1.6) that is either listed on the NDSL or manufactured solely from monomers or reactants listed on the DSL or NDSL must provide the Minister with the information prescribed in Schedule 10 of the Regulations at least 60 days prior to the day on which the quantity of substance manufactured or imported exceeds 10 000 kg in a calendar year.

If the substance is a biopolymer, the notifier is required to provide, in addition to the Schedule 10 information, the information specified in items 1–4 of Schedule 2 of the Regulations. If the biopolymer is a nucleic acid, the notifier is also required to provide the information specified in items 5 and 6 of Schedule 2 of the Regulations.

Health toxicity endpoints referred to in item 4 of Schedule 10 of the Regulations are not required if the polymer is a non-RRR polymer solely due to the presence of any of the following functional groups:

a) aldehydes whose functional group equivalent weight (FGEW, see section 3.3.1.8) is less than or equal to 1 000 daltons;
b) vinyl ethers whose FGEW is less than or equal to 5 000 daltons; or
c) sulphonic acids whose FGEW is less than or equal to 5 000 daltons.

4.9.2 Polymers with High Release and/or Significant Public Exposure

Every notifier who manufactures or imports a polymer that is either listed on the NDSL or manufactured solely from monomers or reactants listed on the DSL or NDSL and

a) that is released to the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment; and/or
b) where the public may be significantly exposed to the polymer in a product

must provide the Minister with additional test information as prescribed in subsections 11(2) and/or 11(3) of the Regulations, respectively, at least 60 days prior to the day on which the quantity of substance manufactured or imported exceeds 50 000 kg in a calendar year. The additional required information is indicated in the following sections.

This additional information is not required if the polymer is a non-RRR polymer solely due to the presence of any of the following functional groups:

a) aldehydes whose FGEW is less than or equal to 1 000 daltons;
b) vinyl ethers whose FGEW is less than or equal to 5 000 daltons; or
c) sulphonic acids whose FGEW is less than or equal to 5 000 daltons.

4.9.2.1 Polymers Released to the Aquatic Environment

It is the notifier's responsibility to submit information in paragraph 5(*g*) of the Schedule 10 NSN to support a claim of the substance not being released to the aquatic environment in the quantity indicated above. This information should include any envisioned future use and quantity by other customers and a description of other envisioned applications. To calculate daily release to the aquatic environment, refer to section 6.6.5 of this Guidance Document.

The NS program will assess this information and if it is determined that the substance is released to the aquatic environment in quantities greater than indicated above, the additional information prescribed in subsection 11(2) of the Regulations must be provided. The NS program's determination of whether the substance is subject to the additional information requirements given below will be provided to the notifier. The notifier may submit additional information to support his or her claim and request a re-evaluation of the decision made by the NS program by contacting the Substances Management Information Line. The NS program will review and consider the information submitted.

The additional information required, as prescribed in subsection 11(2) of the Regulations, must include the following:

a) data from a repeated-dose mammalian toxicity test of the polymer of at least 28 days' duration, using the most significant route of potential public exposure to the polymer, namely, oral, dermal or inhalation, in addition to
   i) the age, sex, number, species, strain and source of the animals tested;
   ii) the route by which the polymer is administered and the conditions under which the test is conducted; and
   iii) the dose of the polymer, the vehicle by means of which the polymer is administered and its concentration in that vehicle; and
b) mutagenicity data obtained from an *in vitro* test, with and without metabolic activation, for gene mutations or chromosomal aberrations in mammalian cells.

4.9.2.2 Where the Public May Be Significantly Exposed to the Polymer in a Product

It is the notifier's responsibility to submit evidence in paragraph 5(h) of the Schedule 10 NSN to support a claim of the public not being significantly exposed to the substance in a product. The NS program's determination of whether the substance is subject to the additional information requirements given below will be provided to the notifier. The notifier may submit additional information to support his or her claim and request a re-evaluation of the decision made by the NS program by contacting the Substances Management Information Line. The NS program will review and consider the information submitted.

Since public exposure is dependent on many factors, a single calculation to determine "significant exposure" cannot be applicable to all circumstances without being extremely

conservative. Therefore, the definition of “significantly exposed” will be assessed, by the NS program, on a case-by-case basis. This information should take into consideration such factors as type of use, duration and frequency of use, concentration of the substance in the product and circumstances of exposure that may limit direct public exposure (e.g., whether the substance is consumed during use or is able to migrate from the product). To determine whether the public may be significantly exposed to the polymer in a product, the NS program provides the opportunity for notifiers to submit a PNC request (see section 8.8).

Some examples of consumer applications where significant public exposure of a substance may occur include, but are not limited to, dishwashing detergent, laundry products, soaps, toilet paper, cleaning solutions, waxes, polishes, air fresheners, paints, oils, greases, body lotions, and ink.

If it is determined that the public may be significantly exposed to the polymer in a product, the additional information prescribed in subsection 11(3) of the Regulations must be provided. The additional information required, as prescribed in subsection 11(3) of the Regulations, must include the following:

a) data from a repeated-dose mammalian toxicity test of the polymer of at least 28 days’ duration, using the most significant route of potential public exposure to the polymer, namely, oral, dermal or inhalation, in addition to
   i) the age, sex, number, species, strain and source of the animals tested;
   ii) the route by which the polymer is administered and the conditions under which the test is conducted; and
   iii) the dose of the polymer, the vehicle by means of which the polymer is administered and its concentration in that vehicle;
b) mutagenicity data obtained from an *in vitro* test, with and without metabolic activation, for gene mutations; and
c) data obtained from an *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells or the data from a previously existing *in vivo* mammalian test for chromosomal aberrations that, together with data substantiating that the tissue investigated was exposed to the polymer or its metabolites, permits an assessment of *in vivo* clastogenicity.

4.9.3 Higher-Quantity Non-RRR Polymers Not on the NDSL and Not Manufactured Solely from Reactants Listed on the DSL or NDSL

Every notifier who manufactures or imports a non-RRR polymer (see section 3.3.1.6) not on the NDSL and that contains one or more reactants not on either the DSL or the NDSL must provide the Minister with the information prescribed in Schedule 11 of the Regulations at least 60 days prior to the day on which the quantity of substance manufactured or imported exceeds 10 000 kg in a calendar year.

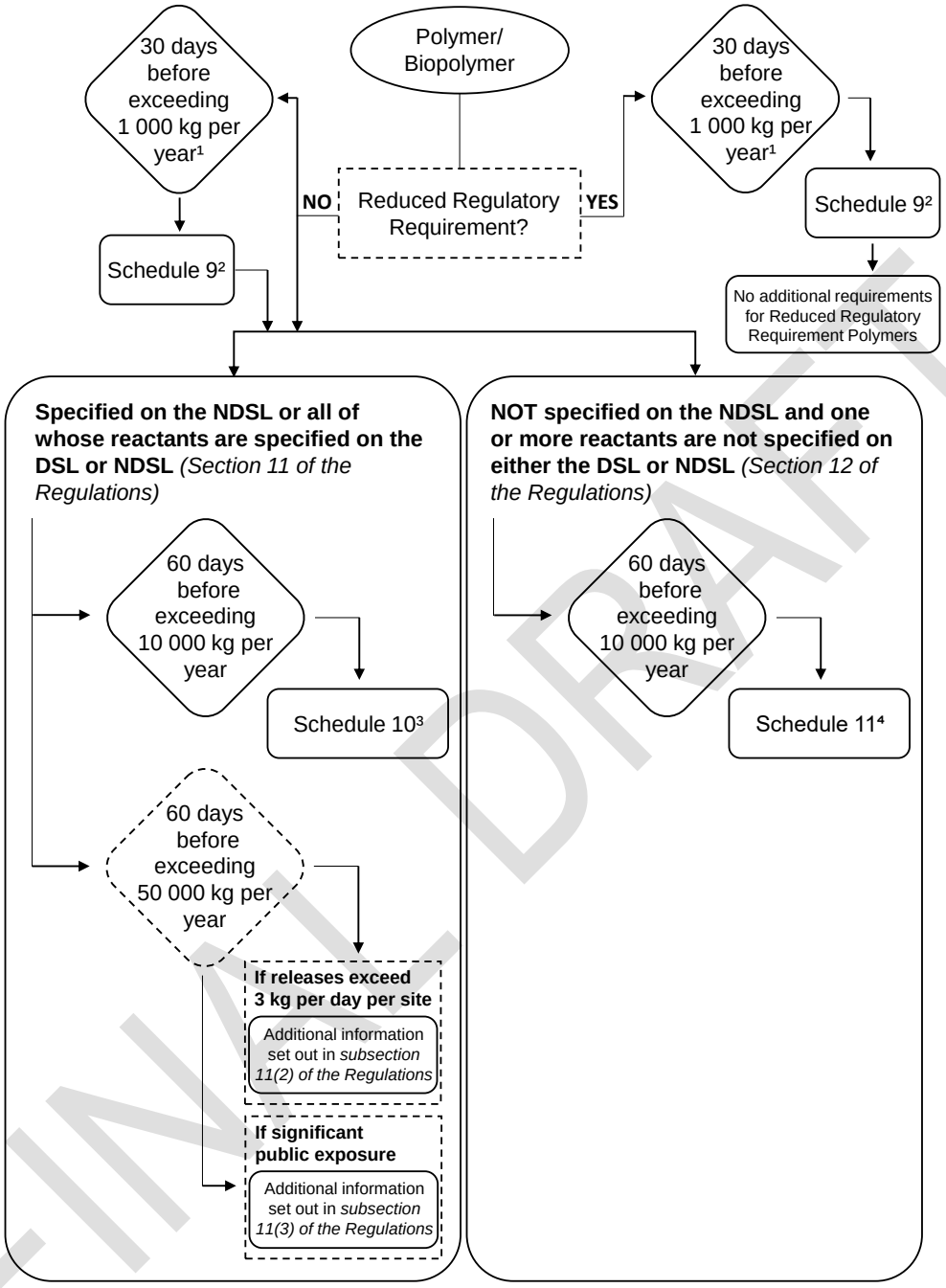
If the substance is a biopolymer, the notifier is required to provide, in addition to the Schedule 11 information, the information specified in items 1–4 of Schedule 2 of the

Regulations. If the biopolymer is a nucleic acid, the notifier is also required to provide the information specified in items 5 and 6 of Schedule 2 of the Regulations.

Health toxicity endpoints referred to in items 5 to 10 of Schedule 11 of the Regulations are not required if the polymer is a non-RRR polymer solely due to the presence of any of the following functional groups:

a) aldehydes whose FGEW is less than or equal to 1 000 daltons;
b) vinyl ethers whose FGEW is less than or equal to 5 000 daltons; or
c) sulphonic acids whose FGEW is less than or equal to 5 000 daltons.

Figure 4-3 Polymers / Biopolymers Other Than Those In Figure 4-1



[1] *Section 10 of the Regulations*.

[2] Additional information specified in Schedule 2 is also required if the polymer is a biopolymer *(see paragraph 10(b) of the Regulations)*.

[3] Not required for Reduced Regulatory Requirement polymers. Also subject to certain exceptions *(see subsection 11(5) of the Regulations)*. Additional information specified in Schedule 2 is also required if the polymer is a biopolymer *(see paragraph 11(1)(b) of the Regulations*. No further information will be required unless: (a) the polymer is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment *(see subsection 11(2) of the Regulations)* or (b) the public may be significantly exposed to the polymer in a product *(see subsection 11(3) of the Regulations)*.

[4] Not required for Reduced Regulatory Requirement polymers. Also subject to certain exceptions *(see subsection 12(3) of the Regulations)*. Additional information specified in Schedule 2 is also required if the polymer is a biopolymer *(see paragraph 12(1)(b) of the Regulations)*.

SECTION 5 — NEW SUBSTANCES NOTIFICATIONS (NSNs)

Subsection 81(1) of the *Canadian Environmental Protection Act, 1999* (the Act) prohibits the manufacture or import of any substance that is not on the Domestic Substances List (DSL) unless the notifier manufacturing or importing the substance has provided the prescribed information within the prescribed time and with the prescribed fee (see fee table on the New Substances Notification (NSN) fees webpage[16]); and the period for assessing the information has expired or has been terminated early (see section 9.3.7.1). The prescribed information specified in the Regulations (see Appendix 2) consists of both administrative and technical information described in sections 6.2 through 6.6.

5.1 Matched Notifications

A Matched Notification takes place when a notifier requests that the NS program use information that was previously provided by another notifier for the same substance. Such information may include test requirements or additional information. The notifier who is providing the information must submit a letter of authorization to the NS program indicating his or her NSN reference number as well as the name of the notifier whom he or she is supporting, together with the latter notifier's NSN reference number, if known. When files are matched, there may be a price reduction in the required fees (see NSN fees webpage[16]). This is different from a Third Party Information Supplier Submission (see section 5.2).

5.2 Third Party Information Supplier Submission (Confidential Information Provided by a Third Party)

Any information submitted to the NS program may be claimed as confidential (see section 7). In cases where the notifier is not given access to information that is considered confidential by a Third Party Information Supplier, the information to support the NSN must be supplied directly to the NS program by the Third Party Information Supplier and will be identified as a "Third Party Information Supplier Submission."

To submit a Third Party Information Supplier Submission, the notifier must initiate the NSN process by providing:

- all the administrative information (blocks A.1 to A.15 of the NSN Form; see section 6.2);
- all exposure information, including manufacture, importation, use, transport, exposure, release and disposal information requirements (Part E of the NSN Form; see section 6.6); and
- any other information the notifier has in his or her possession pertaining to the substance.

[16] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

The NSN must also include a reference to the pending Third Party Information Supplier Submission. Once the notifier has initiated the NSN process and has been provided with an NSN reference number, the confidential information required to complete the NSN must be submitted directly to the NS program by the Third Party Information Supplier, referencing the appropriate NSN reference number to which the information is being provided.

If several companies are manufacturing or importing the same substance from the same third party supplier, each notifier must submit individual NSNs to the NS program, and each notifier is responsible for tracking their own manufacture or import quantities. Each NSN will be assigned a different NSN reference number.

If the Third Party Information Supplier has already submitted the confidential information about a substance for one notifier, the same information does not need to be resubmitted for other notifiers. However, a letter of authorization from the Third Party Information Supplier must be sent to the NS program allowing the cross-referencing and use of the information within the original Third Party Information Supplier Submission to complete each subsequent NSN by other notifiers for the same substance. Fee reductions may be applicable (see NSN fees webpage[17]).

5.3 Consolidated Notifications

Consolidated Notifications take place when a notifier simultaneously provides two to six NSNs for substances of the same class and where the technical information provided for one substance is used to address the technical information requirements for the remaining substances. In these cases, a separate NSN reference number is issued for each of the substances captured by the consolidated NSN, but the NSNs are grouped together for the purposes of a common risk assessment. Consolidated Notifications are subject to reduced fees (see NSN fees webpage[17]). Although not required, it is recommended that notifiers who wish to notify a number of very similar substances at one time as Consolidated Notifications do so after consultation with the NS program, through a Pre-notification Consultation (PNC) request (see section 8.8), to ensure that the technical information is sufficient to address the NSN requirements for all substances in question.

5.4 Test Data

The conditions to be met and the test procedures to be followed when developing test data must be consistent with the conditions and procedures set out in the Organisation for Economic Co-operation and Development (OECD) Test Guidelines (TGs) that are current at the time the test data are developed (see section 8.1.1).

[17] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

In addition, the development of certain test data must comply with the practices set out in the “Principles of Good Laboratory Practice” that are current at the time the test data are developed (see section 8.3).

Protocols and laboratory practices that are recommended by the NS program for the generation of experimental data are described in section 8 of this Guidance Document.

Full test reports must be provided for all prescribed test data; summaries will not be accepted. It is important to ensure that the name and/or trade name of the substance indicated in the test report provided correspond to the name and/or trade name in the NSN. Although the values for the test data will be included in the test reports, values and conditions should also be provided in sections B.1, B.2 and B.3 of the NSN Form (see section 6.3).

If literature papers are referenced, a copy of each paper must be provided. If software estimates/models are being used, information about the model (e.g., version of software), the input data and model output must be provided to allow for an assessment of the data by the NS program (see section 8.4.3).

Test data submitted in a previous NSN, PNC request or notice under section 70 of the Act need not be resubmitted; however, the appropriate reference number must be supplied (see “P” code in section 6.1.2).

Explanations of the conditions under which waivers of prescribed information may be granted are provided in section 8.7 of this Guidance Document, and examples are given in Appendix 6.

5.4.1 Nanomaterials

OECD guidance documents and TGs specific to nanomaterials have been published[18], including guidance such as on sample preparation and dosimetry for manufactured nanomaterials, and adopted TGs. It is expected that new guidance and TGs for nanomaterials will be made available in the coming years as the documentation is developed. If no OECD TG is available for any given endpoint, a PNC (see section 8.8) is recommended to ensure the suitability of the proposed methods.

5.5 Record-Keeping Requirements

Pursuant to section 13 of the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations), a notifier who is required to provide information to the Minister of the Environment or the NS program under the Regulations must keep a copy of that information and any supporting data at the notifier’s principal place of business in Canada or at the principal place of business in Canada of a representative of that

[18] http://www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm

notifier. The information and the supporting data must be kept for a period of five years after the year in which the information is provided.

SECTION 6 — THE NEW SUBSTANCES NOTIFICATION FORM

The New Substances Notification (NSN) Form is intended to serve as an aid for complying with the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations). The form is divided into five sections:

Part A: Administrative and Substance Identity Information Requirements;
Part B: Technical Information Requirements;
Part C: Additional Information Required for Biochemicals or Biopolymers;
Part D: Additional Information Requirements; and
Part E: Human and Environmental Exposure Information (Known and Anticipated).

In addition, four Appendices are included in the NSN Form:

Appendix I: New Substances Fees Payment Form;
Appendix II: Substances Functional Use Codes;
Appendix III: Application Codes; and
Appendix IV: Data Codes, Attachments and Confidential Information.

A complete NSN must contain the specific information requirements of Part A, Part B, Part C and Part E, including all test data, laboratory reports, waiver justifications and other attachments necessary to fulfill the requirements set out in the Regulations. Additional information must be listed in Part D. Appendix I is provided as an aid in determining the fee required for each NSN.

If the NSN Form is incomplete or is filled out incorrectly, the submission may be returned to the notifier. The assessment period will not start until the completed information is submitted correctly.

Information that will not fit in the appropriate block on the NSN Form should be included in an attachment.

Subsection 14(2) of the Regulations states that all information must be provided in English or French. Information can be submitted electronically by electronic mail (e-mail), by storage device (e.g., USB thumb drive) or by logging into the Environment and Climate Change Canada Single Window system, at the following website https://ec.ss.ec.gc.ca and reporting via the NSN online form. The New Substances (NS) program does not accept .zip files, .rar files or any other types of compression programs within an e-mail or on a storage device (e.g., USB thumb drive). Alternatively, a copy of any information provided under the Regulations can be submitted on paper to one of the addresses in the Comments and Inquiries section of this Guidance Document.

The NS program will confirm receipt of the NSN and provide an NSN reference number (see section 9.3.2) that will be used in all further correspondence concerning the NSN.

The NSN Form or sections of the NSN Form may be reproduced as often as required. An electronic version of the NSN Form can be obtained from the NS program website at https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notification-forms.html or by contacting the Substances Management Information Line.

6.1 Data Codes, Attachments and Confidential Information

In addition to the list of information requirements, Part B and C of the NSN Form contains additional columns: Required for Schedule; Data Code; Value and Conditions; Attachment Number; Confidential Information; and Justification Provided. The following explains the use for each of these columns. Explanations also appear in Appendix IV of the NSN Form.

6.1.1 Required for Schedule

This is a quick reference column that allows notifiers to determine, at a glance, which Schedule requires the information to be provided. Footnotes also provide additional guidance for exceptions and conditions associated with certain data elements. It is important to note that if the first notification for a substance is a higher Schedule, all of the information prescribed in the applicable lower Schedules is also required.

6.1.2 Data Codes

A Data Code is a reference to indicate whether data are provided; the type of data provided; or whether a request for waiver of information is being submitted. The Data Codes, with explanatory notes, are as follows:

- D = test data on notified substance, recommended test protocol

  This code is used when the data provided were generated on the notified substance using protocols consistent with those listed in Tables 8-1 to 8-4. This code is to be used even if the information is provided under the Additional Information Requirements of the Schedules (see section 6.5).

- A = alternative procedures

  This code is used when the data provided were generated using an alternative test protocol, surrogate data or Quantitative Structure–Activity Relationships (QSARs) (see section 8.4). This code is to be used even if the information is provided under the Additional Information Requirements of the Schedules (see section 6.5).

- W = waiver requested

  This code is used when it is requested that prescribed information be waived under subsection 81(8) of the *Canadian Environmental Protection Act* (the Act). A request for a waiver of prescribed information must be accompanied by

justifications that satisfy any of the waiver criteria listed in the aforementioned subsection of the Act (see section 8.7).

- N/A = not applicable

  This code is used when the Regulations specify that the provision of information is not required under certain conditions. For example, the adsorption–desorption screening test data is not required when water solubility is less than 200 µg/L. This code cannot be used as an abbreviation for “not available.”

- NR = not required

  This code is used when the information has not been provided and is not required for a specific Schedule of the Regulations.

- P = previous NSN reference number, Pre-notification Consultation (PNC) reference number or notice under section 70 of the Act

  This code is used when the notifier has already provided the information to the NS program in a previous NSN; a previous PNC request; and/or a notice under section 70 of the Act. The applicable NSN, PNC or notice under section 70 reference number must be entered in the Attachment Number column.

6.1.3 Value and Conditions

Although complete physico-chemical data must be submitted in test reports (physical state and whether the notified substance is formulated for dispersal in water excepted), the notifier should enter the value and conditions in the appropriate space provided. This information will assist the notifier in organizing data for use in requesting waivers of information; in justifying cases when data are not applicable; and in discussing notifications with NS program officials.

6.1.4 Attachment Number

Notifiers must clearly indicate a reference for accompanying documents (e.g., Attachment 6) so they may be readily located within the NSN. Attachments include the following: justifications for requesting waivers of information; reports of experimental procedures; reports of test results; rationale for submitting alternative data; results and validation of modelling studies; rationales for why information is considered “not applicable”; and information supplemental to a request for confidentiality.

6.1.5 Confidential Information

Notifiers must check the appropriate box to indicate that the information provided is considered confidential (i.e., mark “Y” to indicate that the information provided is considered confidential or mark “N” to indicate that the information provided is not confidential). If the information provided is considered confidential, the notifier should

provide, in the NSN, the supplementary information detailed in section 7.2 of this Guidance Document.

6.2 Administrative and Substance Identity Information Requirements (Part A)

Explanations of the various administrative and substance identity information requirements are provided below. Subsection 14(1) of the Regulations sets out the information required for the administrative requirements of the NSN.

The information requirements listed in blocks A.1 to A.15 of the NSN form must be provided for all substances that are subject to any Schedule in the Regulations.

6.2.1 Signature Page, Confidentiality Requests and Agreements (Block A.1)

6.2.1.1 Representative of the Resident Manufacturer or Importer of the Substance Identified in Block A.2 or A.3 (Notifier) (Block A.1.1)

The person named in block A.1.1 is the resident notifier who is manufacturing the notified substance in Canada or importing it into Canada (identified in block A.2) or the non-resident notifier (identified in block A.3). The notifier must sign and date the Certification Statement in block A.1.1. The signature is a certification that the information provided in the NSN is accurate and complete to the best of the notifier's knowledge.

6.2.1.2 Agent of the Non-resident Importer of the Substance Identified in Block A.4 (Canadian Agent) (Block A.1.2)

When the importer is not a Canadian resident, block A.4 must be completed and a person must be authorized to act on behalf of the "Non-resident Importer" as the "Canadian Agent". This person must sign block A.1.2 (see section 6.2.4).

6.2.1.3 Toll Manufacturer Statement of Responsibilities identified in block A.7 (Block A.1.3)

For notified substances that are manufactured in Canada on toll (meaning that the person who is actually producing the substance is doing so for the benefit of the notifier), the Toll Manufacturer must sign block A.1.3 (see section 6.2.7). A statement, signed by the Toll Manufacturer, indicates that he or she accepts all compliance responsibilities with respect to the manufacture of the notified substance and any accidental release of the notified substance.

6.2.1.4 Fees Provided (if applicable) (Block A.1.4)

The notifier should indicate the amount of the fee provided as per the *New Substances Fees Regulations* (NSFR) (see fee table on the NSN fees webpage[19]). Appendix I of the NSN Form should also be completed and accompany the NSN.

[19] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

In general, substances subject to notification require fees. However, please note that the NSFR do not apply to biochemicals, biopolymers, research and development substances or to substances that are intended solely for use in products regulated under any other Act of Parliament, including the *Food and Drugs Act* (F&DA), the *Fisheries Act* and the *Health of Animals Act*.

6.2.1.5 Confidentiality Request and Justification (Block A.1.5)

Notifiers must also check the appropriate box to indicate whether the information is confidential or not. If the information is considered Confidential Business Information (CBI), the notifier must provide, in the NSN, the supplementary information detailed in section 7.2 of this Guidance Document. A separate justification is required for substance identity and the other elements of the NSN.

Checking the box entails the following:

- **Name of manufacturer or importer** : The link of the substance identity to the corporation or persons in any or all of blocks A.1.1, A.1.2, A.1.3, A.2, A.3, A.4, A.5 and A.6 is confidential.

- **Activity with the substance (located in block A.12)**: The fact that the corporation identified in block A.2 manufactures and/or imports the substance at the site identified in A.7, A.8, or at any site indicated on any attachment provided with this NSN Form, is confidential.

- **Quantity of substance (located in block A.10)**: The quantity of substance the notifier anticipates exceeding, as indicated in block A.10, as well as the expected date of the exceedance, as indicated in block A.11, are confidential.

- **Substance Identity (if checked, please complete block A.18)**: The identity of this substance as indicated in block A.16 and A.17 is confidential. The supplemental information described in section 7.2 and Appendix 5 of this Guidance Document (Masking of Substance Names) must accompany a confidential substance identity claim.

In addition, a company requesting confidentiality for the above submitted information must describe the nature of the confidentiality by selecting the following criteria which the company deems applicable in block A.1.5:

a) it is a trade secret of the submitter;
b) it is information of a financial, commercial, scientific or technical nature that is treated consistently in a confidential manner by the submitter;
c) its disclosure could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, the submitter; or

d) its disclosure could reasonably be expected to interfere with contractual or other negotiations of the submitter.

6.2.1.6 Limited Disclosure Agreement (Block A.1.6)

This is not a mandatory block. It allows Environment and Climate Change Canada to disclose information, regarding the substance, including information for which a confidentiality request is made, with the New Chemicals Management Branch of the United States Environmental Protection Agency (US EPA) and/or the European Chemicals Agency (ECHA) and/or the Australian Industrial Chemicals Introduction Scheme (AICIS). To share the information with one of these agencies, check the associated box.

6.2.1.7 Information Sharing Agreement (Block A.1.7)

Instances may occur where a substance has been notified but has not been added to the Domestic Substances List (DSL), because the notified substance did not meet all of the criteria in section 87 of the Act; risk management measures were taken on the notified substance; or the assessment or processing of the NSN is still in progress. In such cases, any other notifier intending to manufacture or import that substance will be required to provide a complete NSN. To reduce both duplicate testing and the expense of developing information for an NSN, the NS program provides an opportunity for notifiers of a common substance to exchange data through the use of an Information-Sharing Agreement (ISA). There are no additional fees required for using the ISA.

An ISA starts when a notifier provides the NS program with

1) documentation of intent to manufacture or import a particular substance; and
2) authorization to release the name, address and phone number of the technical contact within the company to any other company that also meets these two criteria.

Documentation of intent to manufacture or import a substance may be either an NSN or a Notice of *Bona Fide* Intent to Manufacture or Import (see section 2.3.1). After receipt and acceptance of this documentation, the NS program will conduct a search for ISA candidates and, if any exist, will simultaneously provide each notifier with the name of the other company or companies and the name, address and phone number of the technical contact for each company. The NS program's contribution to the process will end at this point, and the notifiers may then proceed to negotiate an ISA.

If a notifier is willing to enter into an ISA, the ISA Authorization block (Block A.1.7) must be checked.

6.2.2 Corporate Headquarters of the Resident Manufacturer or Resident Importer (Principal Place of Business in Canada) (Block A.2)

A notifier who is a Canadian resident and is manufacturing a substance in or importing a substance into Canada must provide

a) the contact name and title of the Canadian notifier;
b) the Canadian Federal Business Number;[20]
c) the name and address of the manufacturing or importing company;
d) the telephone number (including area code), as well as the e-mail address, of the manufacturer or importer of the notified substance; and
e) the preferred language of correspondence.

If the importer or manufacturer is not located in Canada, skip to block A.3.

6.2.3 Corporate Headquarters of the Non-resident Importer (Block A.3)

When a foreign company or "Non-resident Importer" is the "Importer of Record," as shown on the Canadian Customs coding form (Form B3-3) as issued by the Canada Border Services Agency, and

a) possesses a "Canadian Importer" status;
b) has "Importer of Record" status; and
c) is importing the notified substance into Canada

the foreign company or "Non-resident Importer" must leave block A.2 blank and provide the information required in block A.3:

a) the contact name and title of the "Non-resident Importer";
b) the civic and postal addresses, telephone number (including area code), and e-mail address of the "Non-resident Importer" of the notified substance; and
c) the preferred language of correspondence.

When the notifier is a "Non-resident Importer," then the notifier must identify, under paragraph 14(1)(b) of the Regulations, a person resident in Canada who is authorized to act on the notifier's behalf as the "Canadian Agent" (see sections 1.4.2 and 6.2.4).

6.2.4 Canadian Agent of the Non-resident Importer (needed if block A.3 is applicable) (Block A.4)

As previously stated, subsection 14(3) of the Regulations states that if the notifier who provides the information under the Regulations is not a resident of Canada, the notifier must identify, under paragraph 14(1)(b) of the Regulations, a person resident in Canada who is authorized to act on the notifier's behalf as the "Canadian Agent."

Therefore, when a "Non-resident Importer" (see section 6.2.3) is the "Importer of Record" on the Canadian Customs documentation for the notified substance being imported, information about the "Canadian Agent" must be provided.

When a "Canadian Agent" is required, the following information must be provided:

[20] The Canadian Federal Business Number is a 9-digit identifier which enables businesses to simplify their dealings with federal governments in Canada. Its purpose is to assign each registered business its own unique number. Visit https://www.canada.ca/en/services/taxes/business-number.html for more information.

a) the signature of the “Canadian Agent” in block A.1.2;
b) all information of the “Non-resident Importer” in block A.3 (see section 6.2.3); and
c) the name, title, Canadian Federal Business Number, company, address, telephone number (including area code), e-mail address, and the preferred language of correspondence of the “Canadian Agent” in block A.4.

If a “Non-resident Importer” provides the information under the Regulations and does not provide the required information about the “Canadian Agent,” the NSN will be considered incomplete and will be returned.

If the “Non-resident Importer” has more than one Canadian customer for the same notified substance, NSNs are not required for each customer as long as the “Non-resident Importer” is recognized as the “Importer of Record” for all shipments going to his or her customers. Yearly import quantities should be tracked by both the “Canadian Agent” and the “Non-resident Importer” to ensure that subsequent higher-quantity notification obligations are met.

The notifier may request that he or she be copied on all correspondence; however, the “Canadian Agent” is legally required to receive all notices or correspondence that may be sent in relation to the NSN and to keep a copy of the complete NSN including the confidential information (except in the case where a Third Party Information Supplier is used) and all correspondence and supporting data with respect to the NSN, for a period of five years after the end of the year in which the information is provided (see section 13 of the Regulations).

6.2.5 Third Party Information Supplier (needed if the technical information in Part B is provided by a third party) (Block A.5)

If any, or all, of the confidential technical information from Part B of the NSN Form is being provided by a person who is not the notifier (third party), the name and title, the address, the Canadian Federal Business Number (if applicable), the company name, the telephone number (including area code), the e-mail address and the preferred language of correspondence of the Third Party Information Supplier must be provided in block A.5.

6.2.6 Technical Contact (Block A.6)

The name of a person who is familiar with the content of the NSN and can assist in resolving issues pertaining to ambiguous, incomplete or missing information must be provided. This person must be identified by his or her name, title, company name and Canadian Federal Business Number (if applicable), address, telephone number (including area code), e-mail address and the preferred language of correspondence. The technical contact need not be a resident of Canada but must be familiar with the nature and content of the NSN.

6.2.7 Proposed Site of Manufacture in Canada, including Toll Manufacturing (Block A.7)

For notified substances that are manufactured in Canada, the notifier must provide the contact name and title, the Canadian Federal Business Number, the company name and the civic address of the site of manufacture of the notified substance in Canada. If there is more than one site of manufacture, all must be provided in an attachment.

For notified substances that are manufactured in Canada on toll (meaning that the person who is actually producing the substance is doing so for the benefit of the notifier), the notifier must provide the following information:

a) the contact name and title, the company name and the Canadian federal Business Number of the toll manufacturer;
b) the address and telephone number (including area code), as well as the e-mail address, of the toll manufacturer; and
c) all required information about the manufacturing facility as described in section 6.6.

6.2.8 Proposed Port of Entry into Canada (Block A.8)

For notified substances that are imported into Canada, the notifier must identify the port of entry into Canada of the notified substance; this identification should include at least the city and province. If there is more than one port of entry, all of them must be identified in an attachment.

Recognized ports of entry are listed at https://www.cbsa-asfc.gc.ca/do-rb/services/menu-eng.html.

6.2.9 Previous New Substances Notification Number/Pre-Notification Consultation Number or Other Consultative Process (Block A.9)

All Schedules require the notifier to provide any previous NSN reference numbers, PNC reference numbers or other consultative process reference numbers, if one has been assigned, and the date (YYYY-MM-DD) of the submission of that information.

6.2.10 Quantity (Block A.10)

The notifier must indicate the prescribed annual quantity that triggers the requirement to notify.

A notifier may, if he or she wishes, opt to immediately submit the highest notification Schedule required, as long as the lowest prescribed quantities for the lowest Schedule are respected and the NSN is submitted within the timeframe prescribed for the highest Schedule.

6.2.11 Date When the Amount in Block A.10 Is Expected to Be Exceeded (Block A.11)

The notifier must provide the date on which the trigger quantity noted in block A.10 is anticipated to be exceeded. This date should be entered in the form of YYYY-MM-DD.

6.2.12 Activity (Block A.12)

The notifier must indicate whether the notified substance will be manufactured in and/or imported into Canada.

6.2.13 Substance Type (Block A.13)

The notifier must check the appropriate boxes to indicate substance type (chemical, biochemical, polymer, biopolymer, special categories, nanomaterial, UVCB[21], present on the Non-domestic Substance List (NDSL)). If the notified substance is a polymer, additional boxes must be checked for information pertaining to reactants and Reduced Regulatory Requirement (RRR) polymer criteria (see section 3.3.1.5). If the notified substance is confidentially listed on the NDSL, the notifier must also provide the Confidential Substance Identity Number.

6.2.14 Schedule Number (Block A.14)

The appropriate Schedule being provided must be selected for the type of substance that is being notified. NSNs for biochemicals or biopolymers must also contain specific items from Schedule 2 of the Regulations. In these cases both the notified Schedule and Schedule 2 should be checked.

6.2.15 Describe Anticipated Uses of the Substance (Blocks A.15.1 to A.15.6)

The anticipated uses of the notified substance should be entered in block A.15.1. Additional information is also required for certain Schedules and should be provided in Part E.2 of the NSN Form (see section 6.6). If known, the functional use code and application code specified in Appendices II and III of the NSN Form should be provided in blocks A.15.2 and A.15.3.

In block A.15.4, if known, the North American Industry Classification System Code (NAICS) for this Substance should be provided. For more information on NAICS refer to https://www23.statcan.gc.ca/imdb/p3VD.pl?Function=getVD&TVD=307532.

In block A.15.5, the notifier should select whether the substance is intended to be manufactured or imported:

a) solely for use in products regulated by the F&DA;
b) for an industrial, commercial, and/or consumer use other than for use in products regulated by the F&DA; or
c) for use in products regulated by the F&DA and in industrial, commercial, and/or consumer products (dual use).

[21] Unknown or Variable composition Complex reaction product or Biological material

If the notified substance is intended to be manufactured of imported for scenario b) or c) above, the notifier must submit the NSN with the appropriate fees (see fee table on the NSN fees webpage[22]).

For more information regarding the notification of substances used in products regulated by the F&DA, contact the Environmental Assessment Unit of Health Canada by phone at 1-866-996-9913 or (613) 948-3591 or by email at hc.eau-uee.sc@canada.ca.

In block A.15.6, from a green chemistry perspective, the notifier should also indicate whether the new substance is intended to replace another substance or group of substances currently on the market. The chemical name and the Chemical Abstracts Service Registry Number (CAS registry number) of the substituted substance or information on the group of substances as well as benefit or reason for the substitution (e.g., replaces a toxic substance, reduces impact of climate change, replaces ozone-depleting substance) should also be provided.

6.2.16 Chemical Abstracts Service Registry Number (Block A.16)

All Schedules of the Regulations require that the CAS registry number be provided, if such a number can be assigned to identify the notified substance. Schedule 2 of the Regulations additionally requires an Enzyme Commission number to be provided for biochemicals that possess enzymatic capability, if one is available (see section 6.4.2.4).

“Can be assigned” refers to the Chemical Abstracts Service’s (CAS) ability to assign a registry number to the substance of interest. However, in cases where the information cannot be submitted to the CAS, the notifier will be asked to provide a written justification, setting out a reason why a CAS registry number cannot be assigned to the substance. If a CAS registry number is not being assigned, a request for confidentiality must be provided (see sections 6.2.1.5).

If the CAS registry number (or a justification) is not contained in the NSN, the NSN will be deemed as missing mandatory prescribed information and a missing information notice will be issued. The assessment period will not start until all the prescribed information has been received and accepted.

The most precise CAS registry number available for the notified substance must be obtained.

For example, for biochemicals, CAS registry numbers for α-Amylase can be differentiated based on the source organism: 9001-19-8 (α-Amylase, *Aspergillus oryzae*) versus 75496-59-2 (α-Amylase (mouse salivary gland isoenzyme reduced)).

[22] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

For example, for chemicals, CAS registry number 68527-02-6 (chlorinated olefins (C_{12}–C_{24})) would not be acceptable for (*Z*)-1-chloro-5-dodecene; the acceptable CAS registry number for this substance is 71673-24-0.

Sources of existing CAS registry numbers are described in Appendix 4 of this Guidance Document. To obtain information about CAS registry numbers, contact

Chemical Abstracts Service
2540 Olentangy River Road
P.O. Box 3012
Columbus, OH 43210
U.S.A.

Telephone: 614-447-3600
800-848-6538, ext. 3731 (Canada and United States)
Fax: 614-447-3713
Internet: https://www.cas.org/

6.2.17 Explicit Chemical Name of the Substance (Block A.17)

All Schedules require that the exact name be used to identify substances established in accordance with the nomenclature rules of the International Union of Pure and Applied Chemistry (IUPAC) or the CAS. The name should enable an unambiguous chemical structural diagram to be drawn, unless the notified substance is considered an UVCB substance.

For UVCB substances, the terms “reaction products of,” “compounds with” or other acceptable nomenclature may be used. Examples of UVCB substances are

a) carbonic acid disodium salt, reaction products with aniline, *p*-phenylenediamine, sodium sulphide ($Na_2(S_x)$), sulphur and *p*-toluidine;
b) amines, rosin, compounds with 6'-(diethylamino)-3'-hydroxy-3-oxo-spiro[isobenzofuran-1(3*H*),9'-[9H]xanthene]-2'-carboxylic acid and sodium bis[2-hydroxy-benzoato(2-)-O^1,O^2]chromate(1-); and
c) oils, mint, *Mentha arvensis* var. *piperascens*, terpene-free.

UVCB substance names may include a description of the synthesis (e.g., acetylation, alkaline hydrolysis) and, where applicable, the range of possible compositions (e.g., paraffins [petroleum], normal $C_{5–20}$). Information on UVCB composition should be provided in Block A.20. Additional information about the naming of well-defined and UVCB chemicals can be found in Appendix 3 of this Guidance Document.

Polymer and biopolymer nomenclature, including pre-polymers, incorporates the identity of monomers and reactants used in the manufacture of the polymer or biopolymer. The name of the polymer may or may not include monomers or other reactants that are either incorporated into the polymer or charged to the reaction vessel at 2% or less by

weight. However, these substances must be included in the description of the polymer composition (see section 6.2.24). Examples of polymer nomenclature are

a) benzene, ethenyl-, polymer with 1,2-ethanediol, butyl 2-propenoate, (chloromethyl)oxirane, 2,5-furanedione and methyl 2-methylpropenoate; and
b) formaldehyde, polymer with (chloromethyl)oxirane, 4-(1,1-dimethylethyl)phenol, 4,4'-(1-methylethylidene)bis[phenol], methyloxirane polymer with oxirane ether with 1,2,3-propanetriol [(3:1)] and oxirane.

6.2.18 Proposed Masked Name (Block A.18)

If the chemical name of the notified substance is claimed as confidential, a masked name should be provided in accordance with the *Masked Name Regulations*. If the substance identity is claimed confidential, the box “Substance Identity” in block A.1.5 must be checked. Procedures for generating masked names are described in section 7.2 and Appendix 5 of this Guidance Document. These procedures are in place to obtain a balance between protecting CBI while ensuring some degree of transparency.

6.2.19 Known Trade Name(s) or Synonym(s) of the Explicit Chemical Name of the Substance, Including Internal Codes and Test Substance Identifiers (Block A.19)

The known trade names of the notified substance and synonyms of the chemical name must be provided for all Schedules of the Regulations. The concentration of notified substance (% by weight) must also be included for each known trade name, including internal codes and test substance identifiers, especially when used as a test substance to satisfy technical information requirements (see Part B of the NSN Form). Additional information should also be entered in Block A.25 for each name or identifier.

6.2.20 UVCB Composition (Immediate Precursors and/or Major Constituents as Anticipated) (Block A.20)

If the substance is an UVCB substance, the substance name of immediate precursors and/or major constituents as anticipated, the CAS registry number and the range of possible composition expressed in percentages (%) must be provided.

6.2.21 The Structural Formula of the Substance, If Possible, or a Partial Structural Formula (Block A.21)

The structural formula diagram must be provided for chemicals subject to Schedule 1, 5 or 6 of the Regulations.

The structural formula diagram, if possible, or else a partial structural formula must be provided for polymers subject to Schedule 3, 9, 10 or 11 of the Regulations.

In both cases, these diagrams must be made large enough to clearly indicate the identity of all atoms, types of bonds, ionic charges and relevant stereochemistry. If the structure is too large for the space allocated on the reporting form, it should be provided

as an attachment.

For polymers, the number or range of repeating units should be indicated and be correct relative to the number average molecular weight (M_n) (e.g., x = 7-15, y = 10-50). Where applicable, proportions of isomers or tautomeric forms must be indicated.

Additional information and examples of structural formula are provided in Appendix 3 of this Guidance Document.

For biochemicals and biopolymers, a primary structure (amino acid sequence) can be provided as alternative data if a structural formula cannot be provided.

For UVCB substances, if the structural formula of the substance cannot be provided, a partial structural formula that includes immediate precursors should be provided.

Reaction Scheme

In addition, a reaction scheme showing a detailed description of the process for which the notified substance is made is required for polymers that are considered RRR (see section 3.3.1.5).

It can be difficult to establish the final structure of a polymer without an understanding of the reaction sequence because monomers are multifunctional. The provision of detailed reaction scheme information will help confirm the RRR status of the polymer and contribute to more accurate evaluations. The reaction scheme should contain the following information:

- the chemical identity of monomers, pre-polymers, and reactants in the polymer;
- the details of polymer synthesis, including the sequence of the addition of the monomers and reactants, their percentage by weight, and the relative number of moles;
- the nature of the reactions (e.g., hydrolysis, epoxidation, or esterification); and
- the polymer structure and any known by-products.

The reaction scheme does not need to include an engineering diagram outlining such details as reaction vessels or containers for storage and transport; it is not intended to be a process description. The reaction scheme must include monomer and reactant information, as well as a sequence description. Additional information regarding requirements for reaction schemes can be found in Appendix 8.

Note that a reaction scheme is only required for RRR polymers meeting criteria set out in paragraph 9(a) or (b) of the Regulations. A reaction scheme is not required for RRR polymers meeting the criteria set out in paragraph 9(c) of the Regulations or for Non-reduced Regulatory Requirement polymers (non-RRR). However, providing a reaction scheme for polymers not meeting the criteria in 9(a) or (b) of the Regulations can help in the assessment of the notified polymer by illustrating the manufacturing process.

6.2.22 Molecular Formula (Block A.22)

The molecular formula is required for chemicals that are subject to Schedule 1, 5 or 6 of the Regulations and for polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations. An undefined molecular formula may also be acceptable (e.g., for UVCB). The empirical formula must be provided and should identify each of the monomer units. Examples are

a) methyl methacrylate, polymer with ethyl acrylate $(C_5H_8O_2 \times C_5H_8O_2)_x$; and
b) polyoxyethylene sorbitol tetraoleate
$(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_nC_{78}H_{142}O_{10}$

6.2.23 Gram Molecular Weight (Block A.23)

This information is required for chemicals that are subject to Schedule 1, 5 or 6 of the Regulations. The gram molecular weight should be provided for chemicals with a definite structural formula. For UVCB substances, an estimate or range of molecular weights must be provided, if known.

The number average molecular weight for polymers is discussed in section 6.3.1.14 of this Guidance Document and should be entered into block B.1 of the NSN Form and not in block A.23.

6.2.24 Monomers and Reactants (Block A.24)

This information is required for polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations. Reactants include compounds such as free radical initiators, cross-linking agents, chain-terminating agents, neutralizing agents and chain-transfer agents including monomers that become part of the polymer. The name, CAS registry number and percentage by weight of each reactant must be provided. Reactants, either incorporated into the polymer or charged to the reaction vessel at 2% or less by weight in the manufacture of the polymer, must also be reported, even if they were not included in the name of the polymer. The percentage by weight of the reactants must add up to 100%.

Pre-polymer not on the DSL or NDSL but whose reactants are listed on the DSL or NDSL

If a non-RRR polymer contains a pre-polymer that is not on the DSL or NDSL but all of the pre-polymer's reactants are listed on the DSL or NDSL, it can be considered for notification under a schedule with fewer information requirements, i.e., under schedule 10 instead of schedule 11 for a 10 000 kg trigger quantity.

The term "reactant" is defined in subsection 1(1) of the Regulations as follows:

in respect of a polymer, means a substance that is used in the manufacture of the polymer and becomes part of its chemical composition, and includes a monomer.

For the purpose of deciding whether or not a non-RRR polymer will be eligible for fewer information requirements provided in section 11 of the Regulations (see section 4.7.1), the term “reactant” includes ultimate precursors of pre-polymers.

For example, polymer ABCDE contains reactants A and E which are listed on the DSL and pre-polymer BCD which is not on the DSL or NDSL. Pre-polymer BCD contains reactants B, C and D; pre-polymer reactants B and D are listed on the DSL; pre-polymer reactant C is listed on the NDSL. Therefore, in this case, the notified substance, polymer ABCDE, could be considered for notification under a schedule with fewer information requirements.

If a pre-polymer is used in the manufacture of the notified substance and the pre-polymer is not on the DSL or NDSL but all of its reactants are listed on the DSL or NDSL, the composition data for the pre-polymer must be provided and must include the names and CAS registry numbers for each of its reactants. This is necessary in order to determine whether fewer information requirements apply to the notified substance.

The percentage by weight of the composition of the pre-polymer is also required if a reactive or cationic moieties is present in the pre-polymer (see section 3.3.1.5). This is necessary to determine whether the notified substance is considered RRR.

6.2.25 Additives, Stabilizers and Solvents Present when the Chemical is Tested for Each Name or Identifier Listed in Block A.19 (Block A.25)

This information is required for chemicals that are subject to Schedule 1, 5 or 6 of the Regulations and polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations. Additives are substances that are deliberately introduced into a final product containing the notified substance (e.g., stabilizers, emulsifiers, solvents and anti-oxidants) that are present when the chemical is tested.

For each name or identifier of the test substance identified in block A.19 used to satisfy the technical information requirements (see Part B of the NSN Form), its compositional information must be provided. This includes the substance name, CAS registry number and concentration by weight of each component. The percentage by weight of the components must add up to 100%.

6.2.26 Degree of Purity in Its Technical Grade Composition (Block A.26)

This information is required for chemicals that are subject to Schedule 1, 5 or 6 of the Regulations.

6.2.27 Impurities and their Concentration by Weight (Block A.27)

This information is required for substances that are subject to Schedule 1, 3, 5, 6, 9, 10 and 11 of the Regulations.

Impurities are substances that are present in low concentrations in the final product containing the notified substance, but are not necessary for its intended use (e.g., unreacted starting materials, reaction by-products). The name, CAS registry number and concentration by weight of each impurity must be provided, if known.

6.2.28 Safety Data Sheet (Block A.28)

All Schedules require that a Safety Data Sheet (SDS) be provided if available. An SDS, as defined in section 2 of the *Hazardous Products Act* must be provided if one has been prepared.

6.3 Technical Information Requirements (Part B)

All prescribed technical information must be addressed by submitting test data, alternative data or waiver requests (see section 8). Compositional information must be provided for each test substance used to satisfy the technical information requirements (see section 6.2.25). The onus is on the notifier to provide acceptable information. Explanations of the information requirements, which appear in the various Schedules of the Regulations, are provided in order to assist with the generation and compilation of the technical data prescribed in the Regulations. These explanatory notes include details such as under which Schedules the information is required; the conditions under which various tests are required; and what constitutes complete and adequate information according to the NS program.

Part B of the NSN Form contains three sections:

- B.1 Physical and Chemical Information;
- B.2 Ecotoxicity Information; and
- B.3 Health Toxicity Information.

Explanatory notes for many of the technical information requirements are given in the following sections of this Guidance Document.

6.3.1 Physical and Chemical Information (Block B.1)

Guidance documents specific to nanomaterials and revisions to the Organisation for Economic Co-operation and Development (OECD) Test Guidelines (TGs) have been published in recent years and should be incorporated into any testing strategies.

6.3.1.1 Melting Point

This test is required for chemicals that are subject to Schedule 5 or 6 of the Regulations. A melting point between -25 °C and 300 °C must be provided as a single value or a range of values. However, if the value is outside this temperature range, the information may be indicated as "< -25 °C" or "> 300 °C." In cases where the notified substance undergoes a chemical reaction (e.g., degradation, decomposition, rearrangement) other than melting, then the temperature at which the reaction occurs must be reported. As alternative data, a pour point, softening point or sublimation point can be provided instead of a melting point, when appropriate. In the case of biochemicals and biopolymers, an isoelectric point can be provided as alternative data.

6.3.1.2 Boiling Point

This test is required for chemicals that are subject to Schedule 5 or 6 of the Regulations. A boiling point between -50 °C and 300 °C must be provided as a single value or a range of values. However, if the value is outside this temperature range, the information may be indicated as "< -50 °C" or "> 300 °C." In cases where the notified substance undergoes a chemical reaction (e.g., degradation, decomposition, rearrangement) other than boiling, then the temperature at which the reaction occurs must be reported.

6.3.1.3 Water Solubility

Water solubility is required for chemicals that are subject to Schedule 5 or 6 of the Regulations.

Water solubility is also a relevant property for nanomaterials, but it is necessary to distinguish between solubility and dispersibility. Information about dispersion of nanomaterials (e.g., colloidal dispersion) should be provided. For certain nanomaterials such as metal oxides, the relevant dissolution test is recommended. For relevant information, consult OECD Guidance Document No. 29.[23]

6.3.1.4 Water Extractability

Water extractability is required for polymers that are subject to Schedule 10 or 11 of the Regulations.

Testing should be performed according to OECD TG 120, a modified version of the shake flask method from OECD TG 105. Testing according to the OECD TG 105 column elution method does not address the required endpoint and is therefore not acceptable. The NS program also recommends the OECD TG 120 for testing polymers containing water-reactive functional groups. Additional information is available in

23 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2001)9&doclanguage=en

Depending on the nature of the new polymer, testing must be performed at the pH defined in the Regulations, i.e., anionic and neutral polymers at pH 7, cationic polymers at pH 2 and 7, and amphoteric polymers at pH 2, 7 and 9. Results must be reported in % extractable.

6.3.1.5 Vapour Pressure

This test is required for chemicals that are subject to Schedule 5 or 6 of the Regulations. However, vapour pressure is not required if the chemical has a standard boiling point below 0 °C.

6.3.1.6 Density

Density is required for chemicals that are subject to Schedule 5 or 6 of the Regulations.

6.3.1.7 Octanol/Water Partition Coefficient

The octanol/water partition coefficient is required for chemicals that have a water solubility of less than or equal to 5 g/L that are subject to Schedule 5 or 6 of the Regulations. However, there is no water extractability cut-off for polymers; therefore, the octanol/water partition coefficient is required for all substances that are subject to Schedule 10 or 11 of the Regulations.

6.3.1.8 Hydrolysis as a Function of pH

This test is required for chemicals that have a water solubility of greater than or equal to 200 µg/L that are subject to Schedule 6 of the Regulations.

This test is also required for chemicals that have a water solubility of greater than or equal to 200 µg/L that are subject to Schedule 5 of the Regulations and are listed on the NDSL, and meet the high release criteria (subsection 7(2) of the Regulations) (see section 4.4.3.1). The identity of any known hydrolysis products must also be provided.

This test is also required for polymers that are subject to Schedule 10 or 11 of the Regulations and have a water extractability determined to be greater than 2%. The identity of any known hydrolysis products must also be provided.

6.3.1.9 Ready Biodegradation

A ready biodegradation test is required for chemicals that are subject to Schedule 5 or 6 of the Regulations. The identity of any known products of biodegradation must also be provided.

This test is also required for polymers that are subject to Schedule 11 of the Regulations. The ready biodegradation test is required on the water-soluble portion of the polymer unless the polymer has a water extractability at pH 7 of less than or equal to 2% or is a branched silicone or siloxane polymer.

This test must comply with Good Laboratory Practice (GLP) (see section 8.3).

6.3.1.10 Adsorption–Desorption

This test is required for chemicals that have a water solubility of greater than or equal to 200 µg/L and are subject to Schedule 6 of the Regulations.

This test is also required for chemicals that have a water solubility of greater than or equal to 200 µg/L that are subject to Schedule 5 of the Regulations and are listed on the NDSL, and meet the high release criteria (subsection 7(2) of the Regulations) (see section 4.4.3.1).

6.3.1.11 Spectroscopy

This test is required for chemicals that are subject to Schedule 6 of the Regulations. At least one spectrum suitable for characterization of the chemical is required (e.g., Infrared (IR), Ultraviolet (UV), Nuclear Magnetic Resonance (NMR)). Details of the methodology used (e.g., solvent, ionization technique, field strength, band width, instrumentation) must also be provided. UV spectra should include the range down to 290 nm.

6.3.1.12 Formulated for Dispersal in Water

This information is required for polymers subject to Schedule 3, 10 or 11 of the Regulations. The degree of dispersibility need not be determined; however, if the polymer is formulated for dispersal in water, this must be stated. The requirement for this data point will be satisfied by indicating “yes” or “no” in the column of Block B.1 of the NSN form.

6.3.1.13 Physical State

The physical state of the polymer is required for polymers subject to Schedule 3, 10 or 11 of the Regulations. The requirement for physical state will be satisfied with an appropriate term (e.g., “solid”, “wax” or “liquid”) in the column of Block B.1 of the NSN form.

6.3.1.14 Number Average Molecular Weight

This test is required for polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations. Generally, if the polymer is available in series of different molecular weight compositions, information must be developed using the lowest M_n composition. However, pre-existing information developed on higher molecular weight compositions should also be submitted. The M_n information must include the test procedures used and the chromatogram, calibration curve and slice tables produced during the test. There are different techniques available to determine the M_n, but the one most often used is Gel Permeation Chromatography (GPC). Additional information about what needs to be provided and frequently encountered difficulties with GPC data can be found in Appendix 7 of this Guidance Document.

If the notified substance's solubility is greater than or equal to 2% in a suitable solvent for the substance, the M_n must be determined on the extractable portion of the notified substance (e.g., if only 5% of the polymer is soluble, then the M_n must be determined on this 5% portion).

When the polymer is insoluble (<2%) in solvent systems typically used for GPC, then solubility data over a range of different solvents should be provided. For example, insolubility in typical solvents could indicate a highly cross-linked polymer and alternate methods for M_n determination should be employed or a waiver request should be submitted along with the insolubility results. The M_n for a pre-polymer could also be provided as alternate data in this example.

Only a target M_n is required for polymers that are manufactured or imported as research and development substances and that are subject to Schedule 3 of the Regulations.

6.3.1.15 Residual Constituents with Molecular Weights Less than 500 Daltons and Less than 1 000 Daltons

This information is required for polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations, except for Schedule 3 that is for research and development substances.

The percentage of residual constituents must be determined on the composition that has the lowest M_n of any composition intended for manufacture or import.

6.3.2 Ecotoxicity Information (Block B.2)

The actual number and type of ecotoxicity tests that must be performed on a substance depend on Schedule number and/or the most sensitive species with regard to the substance. Full test reports must be provided; summaries will not be accepted. Compositional information must be provided for each test substance used to satisfy the technical information requirements (see section 6.2.25).

For all ecological toxicity information requirements for nanomaterials, the *OECD Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials*[24] should be consulted. Guidance documents specific to nanomaterials and revisions to the OECD TGs have been published in recent years and should be incorporated into any testing strategies.

[24] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2012)40&doclanguage=en.

It is recommended that the particle size distribution be measured by number count in order to better account for the presence of smaller nanoscale particles. If information about primary particle size and particle size distribution is not provided, and the NS program believes that the substance could be a nanomaterial, the substance will be treated as a potential nanomaterial for risk assessment and risk management purposes.

6.3.2.1 Acute Aquatic Toxicity

One or more of these tests are required for chemicals subject to Schedule 5 or 6 of the Regulations and for polymers subject to Schedule 10 or 11 of the Regulations.

For chemicals subject to Schedule 5 of the Regulations, data from one acute fish, daphnia or algae toxicity test are required.

For chemicals subject to Schedule 6 of the Regulations, data from the remaining two ecotoxicity tests (that were not completed for the submission of Schedule 5) are required.

For polymers subject to Schedule 10 of the Regulations, unless the polymer has a water extractability at pH 7 of less than or equal to 2%, data from an acute toxicity test for the most sensitive species (fish, daphnia or algae) or, if the sensitivity of these three species is unknown, data from an acute algae toxicity test are required.

For polymers subject to Schedule 11 of the Regulations and that have a water extractability at pH 7 of greater than 2%, data from the following tests are required:

a) if the sensitivity of the three species is known, an acute toxicity test of the polymer for each of the two most sensitive species: fish, daphnia or algae;
b) if the sensitivity of only one species is known and that species is not algae, an acute algae toxicity test and either a fish or daphnia acute toxicity test selected on the basis of the most sensitive of these species; or
c) if the sensitivity of only one species is known and that species is algae or if the sensitivity of the three species is unknown, an acute algae toxicity test and either a fish or daphnia acute toxicity test.

These tests must comply with GLP (see section 8.3).

6.3.3 Health Toxicity Information (Block B.3)

For all health toxicity information requirements, the following test information must also be provided:

a) the age, sex, number, species, strain and source of the animals tested;
b) the route by which the substance is administered and the conditions under which the test is conducted; and
c) the dose of the substance, the vehicle by which the substance is administered and the concentration of the polymer in the vehicle.

Compositional information must be provided for each test substance used to satisfy the technical information requirements (see section 6.2.25).

For all health toxicity information requirements for nanomaterials, the *OECD Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials* should be consulted. Guidance documents specific to nanomaterials and revisions to the OECD TGs have been published in recent years and should be incorporated into any testing strategies.

It is recommended that the particle size distribution be measured by number count in order to better account for the presence of smaller nanoscale particles. If information about primary particle size and particle size distribution is not provided, and the NS program believes that the substance could be a nanomaterial, the substance will be treated as a potential nanomaterial for risk assessment and risk management purposes.

6.3.3.1 Acute Mammalian Toxicity

This information is required for chemicals subject to Schedule 5 or 6 of the Regulations and for polymers subject to Schedule 10 or 11 of the Regulations. Test animals must be dosed using the same route or routes of exposure that are anticipated to be the most significant route or routes for potential public exposure (e.g., oral, dermal and/or inhalation). In the Regulations, the most significant route of potential public exposure means exposure of the general population in Canada. To select the most appropriate route or routes for testing, the expected concentration of the notified substance in the various environmental media and consumer products and the bioavailability of the substance through ingestion, inhalation and dermal absorption must be considered. The most significant route of exposure to a substance for the general population may be different from exposures for workers in an occupational setting. Consequently, data generated for occupational exposures may not meet the requirement for the most significant route of potential public exposure specified in the Regulations. If it is not evident which route or routes would be the most appropriate for testing under the Act, the NS program (see section 8.8) should be consulted.

For nanomaterials, an acute inhalation toxicity test is generally recommended. A revised Guidance Document on Inhalation Toxicity Testing addressing nanomaterial-specifc issues was published in 2018.[25]

Acute toxicity test data generated after December 16, 2002, using OECD TG 401 will not be considered acceptable to fulfill the regulatory requirements for this endpoint.

These tests must comply with GLP (see section 8.3).

[25] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)28/rev1&doclanguage=en

6.3.3.2 Skin Irritation

Information sufficient to assess skin irritation is required for chemicals subject to Schedule 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations. This information could be obtained from data from validated test methods for the following endpoints:

- skin irritation (e.g., OECD TG 404);
- dermal sensitization (e.g., OECD TG 406), in which the results of adequate grading of dermal responses are provided;
- dermal toxicity (e.g., OECD TGs 402, 410, 411), in which the results of adequate grading of dermal responses are provided; and
- *in vitro* skin corrosion (positive response only) (e.g., OECD TGs 430, 431).

The above list is not intended to be exhaustive. As new methods are developed and validated, the NS program will assess whether they provide sufficient information to permit an assessment of skin irritation.

Properly conducted human patch tests (positive or negative response) may be an acceptable alternative to animal testing. The concentration of notified substance to which individuals were exposed will be a critical factor in deciding on the acceptability of human patch tests. Human use experience may also be an acceptable alternative (positive response only), provided the human use experience is well described, including quantifying the exposure and dermal response as accurately as possible. Anecdotal information from persons handling or exposed to the substance is not an acceptable alternative.

In addition, information for the assessment of skin irritation may be obtained from Quantitative Structure–Activity Relationships, with adequate scientific justification provided by the notifier regarding the validation and applicability domain of the model.

These tests must comply with GLP (see section 8.3).

6.3.3.3 Skin Sensitization

This information is required for chemicals subject to Schedule 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations. Properly conducted human patch tests (positive or negative response) may be an acceptable alternative to animal testing. The concentration of notified substance to which individuals were exposed will be a critical factor in deciding on the acceptability of human patch tests. Human use experience may also be an acceptable alternative (positive response only), provided the human use experience is well described, including quantifying the exposure and dermal response as accurately as possible. Anecdotal information from persons handling or exposed to the substance is not an acceptable alternative.

This test must comply with GLP (see section 8.3).

6.3.3.4 Repeated-Dose Mammalian Toxicity

This information is required for chemicals subject to Schedule 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations. A test report from a study of at least 28 days' duration must be submitted. As described in section 6.3.3.1 of this Guidance document, "Acute Mammalian Toxicity," test animals must be dosed using the most significant route of potential exposure for the general population in Canada.

The above-mentioned test is also required for a chemical that is listed on the NDSL and for a polymer that is listed on the NDSL or all of whose reactants are listed on the DSL or NDSL and where the substance meet the high release criteria; and/or the public may be significantly exposed to the substance in a product (subsections 7(2), 7(3), 11(2) or 11(3) of the Regulations). For additional information about these data points, see sections 4.4.3 and 4.9.2 of this Guidance Document.
This test must comply with GLP (see section 8.3).

6.3.3.5 *In Vitro* Test for Gene Mutations

An *in vitro* test, with and without metabolic activation, for gene mutation is required for chemicals subject to Schedule 5 or 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations.

This test is also required for a polymer that is listed on the NDSL or all of whose reactants are listed on the DSL or NDSL and where the substance meet the high release criteria; and/or the public may be significantly exposed to the polymer in a product (subsections 11(2) and 11(3) of the Regulations). For additional information about these data points, see section 4.9.2 of this Guidance Document.

When this information is required under subsection 11(2) of the Regulations, the notifier may provide, in lieu of this test, an *in vitro* test, with and without metabolic activation, for chromosomal aberrations (see next section).

This test must comply with GLP (see section 8.3).

The OECD Working Party on Manufactured Nanomaterials Workshop on the Genotoxicity of Manufactured Nanomaterials[26] held in Ottawa in November 2013 concluded that the Bacterial Reverse Mutation Test (OECD TG 471) is not a recommended test method for investigation of the genotoxicity of nanomaterials. Instead, it is recommended that the OECD Guidelines for the Testing of Chemicals program should consider modifying the applicability domain within TG 471 accordingly. Information from a Bacterial Reverse Mutation Test may be relevant only in instances where the nanomaterial is very small (e.g., capable of direct penetration of the cellular membrane), soluble, or capable of producing reactive oxygen species. Consequently, *in vitro* genotoxicity testing of particles in mammalian cells (e.g., *in* vitro mammalian cell

[26]Genotoxicity of Manufactured Nanomaterials: Report of the OECD Expert Meeting (http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)34&doclanguage=en).

gene mutation assays, and *in vitro* micronucleus assay) is encouraged in most instances. The *"In vitro* Mammalian Cell Gene Mutation Test" (OECD TG 476) is the assay recommended to fulfill the data requirement for an *in vitro* mutagenicity test (item 7 of Schedule 5 of the Regulations) for a nanomaterial.

6.3.3.6 *In Vitro* Test for Chromosomal Aberrations

An *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells is required for chemicals subject to Schedule 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations.

This test is also required for a chemical that is listed on the NDSL and for a polymer that is listed on the NDSL or all of whose reactants are listed on the DSL or NDSL and where the public may be significantly exposed to the substance in a product (subsections 7(3) and 11(3) of the Regulations). For additional information about these data points, see sections 4.4.3.2 and 4.9.2.2 of this Guidance Document.

When this information is required under subsections 7(3) or 11(3) of the Regulations, the notifier may, in lieu of an *in vitro* test for chromosomal aberrations, submit data from a previously existing *in vivo* mammalian test for chromosomal aberrations, together with data substantiating that the tissue investigated was exposed to the notified substance or its metabolites.

This test must comply with GLP (see section 8.3).

6.3.3.7 *In Vivo* Mammalian Mutagenicity Test for Chromosomal Aberration or Gene Mutation

An *in vivo* mammalian test for chromosomal aberrations or gene mutations or another indicator of mutagenicity that, together with data substantiating that the tissue investigated was exposed to the substance or its metabolites, generates an assessment of *in vivo* mutagenicity acceptable to the NS program, is required for chemicals subject to Schedule 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations.

Criteria for "evidence that the tissue investigated was exposed to the substance or its metabolites" and for what constitutes an "indicator of mutagenicity" and an assessment "acceptable to the NS program" are described in Appendix 13 of this Guidance Document.

Some flexibility is allowed in the choice of *in vivo* test, so that the most appropriate test can be selected for the substance. The choice of *in vivo* test should be based on results from *in vitro* genotoxicity tests, the structure and mechanism of action of the substance, and developments in the field of genotoxicity.

This test must comply with GLP (see section 8.3).

6.3.4 Regulatory Exemptions: Health Toxicity Tests Not Required for Certain Polymers

The information required for polymers with high release and significant public exposure (see section 4.9.2) that is prescribed in subsections 11(2) and 11(3) of the Regulations, as well as the health toxicity tests described in section 6.3.3 of this Guidance Document, are not required for polymers that fall under one of the classes listed in Table 6-1.

Table 6-1 Exceptions from Health Toxicity Tests for Polymers

Polymer class	Definition
RRR polymers[a]	As defined in section 3.3.1.5 of this Guidance Document.
Aldehyde	Non-RRR polymers *solely* due to the presence of aldehydes whose FGEW[c] is less than or equal to 1 000 daltons.
Vinyl ether	Non-RRR polymers *solely* due to the presence of vinyl ethers whose FGEW is less than or equal to 5 000 daltons.
Sulphonic acid	Non-RRR polymers *solely* due to the presence of sulphonic acids whose FGEW is less than or equal to 5 000 daltons.

[a]RRR polymers – Reduced Regulatory Requirement polymers
[b]Non-RRR polymers – Non-reduced Regulatory Requirement polymers
[c]FGEW – functional group equivalent weight

6.3.5 Waivers for Health Hazard Toxicity Data for Polymers

Table 6-2 lists, in two columns, some examples of polymers for which waivers could be granted and some examples of polymers for which waivers are less likely to be granted for health toxicity tests. This table is subject to change as more information becomes available. These updates will be provided through the NS program website at https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html. These waivers are evaluated on a case-by-case basis; although not required, the NS program provides the opportunity for notifiers to submit a PNC request (see section 8.8), while the NSN is being prepared, to determine whether the waivers are acceptable.

Table 6-2 Waivers for Health Hazard Toxicity Data for Polymers

Polymers for which waivers for health toxicity tests could be granted	Polymers for which waivers for health toxicity will less likely be granted
Non-RRR polymers[a] solely due to the presence of the following cationic or potentially cationic groups: primary, secondary or tertiary amine groups; carbodiimides; or sulphoniums.	1) Polymers containing other cationic groups (such as quaternary amines, hindered amines, azides, isocyanates (free and blocked) and phosphoniums) (see section 8.7.2). 2) Acute and repeated-dose toxicity tests will not be waived for cationic polymers with an M_n greater than 10 000 daltons if inhalation is expected to be the most significant route of exposure for the general population based on expected use or if the substance is used in products regulated under the F&DA[b]. 3) Polymer for which inhalation is the main route of exposure (aerosol) or the intended uses are in personal care products and/or children's toys.

[a]Non-RRR polymers – Non-reduced Regulatory Requirement polymers
[b]F&DA – *Food and Drugs Act*

6.4 Additional Information Required for Biochemicals or Biopolymers (Part C)

Additional information is required for biochemicals and biopolymers manufactured or imported, including substances being manufactured or imported under one of the special categories indicated in section 3.4 of this Guidance Document. The following information is required to address the nature of the production process (e.g., living organism) and the potentially unique biological activity of enzymes and nucleic acids.

6.4.1 Information Required for the Production Organism (Block C.1)

6.4.1.1 Identification, Source and History of the Production Organism

The identification of the production organism and the organ, if applicable, from which the substance is isolated is information required for biochemicals and biopolymers subject to any Schedules of the Regulations. Taxonomic designations should follow the International Code of Nomenclature and standard taxonomic sources. The organism used to produce the biochemical or biopolymer must be identified at least to the species level and to a level that distinguishes the organism from closely related pathogenic species. The identity of the organism should be substantiated using methods that are

consistent with those currently used in microbial taxonomy. Where the organism is genetically modified, the host organism and the sources of exogenous genetic material (donor organisms) should be identified.

In addition, this information must include:

a) any synonyms, common and superseded names for the organism, if known, including synonyms and superseded names of the species must be provided. All known internal company codes and culture collection designations must also be provided, and

b) its original source and history: information about the historical record of the notified micro-organism from its original source of isolation until final product development should be provided. This information includes any strain bank and accession numbers (e.g., American Type Culture Collection) and the history of storage and culture conditions. Copies of any published reports of the strain's isolation, characterization, and any previous genetic modifications should be provided.

Where the substance's name is claimed as confidential, an acceptable masked name should be provided in accordance with the *Masked Name Regulations*. Guidance for masking micro-organism names is given in the *Guidance Document for the Notification and Testing of New Living Organisms.*

6.4.1.2 Adverse Environmental or Human Health Effects of the Production Organism

This information is required for biochemicals and biopolymers subject to any Schedule of the Regulations. This information should include a description of any known adverse environmental or human health effects associated with exposure to the production organism. This information requirement should be supported with a thorough literature search.

Documentation submitted based on a literature search should include a copy of the literature search performed, indicating:

- the time period covered by the search;
- the date the search was conducted;
- the information sources (databases used);
- titles and abstracts of the search results in French or English; and
- search strategy and search terms used.

A summary of the findings from the literature search that clearly shows how they are relevant to the information requirement should be provided for each information requirement addressed. If most of this information is available in recent reports, literature dating back a number of years may not be necessary. Where recent reports are unavailable, inconclusive, incomplete or contradictory, a more extensive search

over a longer time period should be conducted. Full copies of any papers cited, including patents, must be provided in your response in English or French.

When the information provided is based upon a literature review, it must be conducted within six months of the submission of the notification and should cover major scientific information sources.

If a literature search is conducted to address a specific information requirement and there are no results for the literature search performed, this must be clearly indicated in the response for that information requirement and include all information regarding the literature search performed. Note that, in this case, the search should be expanded to cover the past 30 years.

6.4.1.3 Concentration of Viable Production Organism (including in End-use Products)

This information is required for biochemicals and biopolymers subject to any Schedule of the Regulations. The concentration of the viable production organism in the biochemical or biopolymer and, if known, in end-use products must be provided with specific units of measure (e.g., CFU/mL).

Production organisms that are present in the notified substance may be subject to the *New Substances Notification Regulations (Organisms)*, and the level of these organisms should therefore be determined and provided, together with a description of the assay method. In addition, the presence of viable organisms in a substance may result in an exposure to an organism or its metabolic products and could be a potential hazard.

During the research and development stage of manufacturing, the number of persons exposed to a substance is usually limited, and the pilot-scale manufacturing process is not necessarily representative of the conditions that will exist during full-scale production. For these reasons, determination of the level of production organism(s) in the notified substance is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture and that are subject to Schedule 1 or 3 of the Regulations.

6.4.1.4 Method of Separation of the Production Organism from the Biochemical or Biopolymer

This information is required for biochemicals subject to Schedule 1, 5 or 6 of the Regulations and biopolymers subject to Schedule 3, 10 or 11 of the Regulations. This information must include a description of the method(s) used to separate the production organism from the biochemical or biopolymer.

This information is not required for research and development substances subject to Schedule 1 or 3 of the Regulations.

6.4.2 Information Required for Biochemicals or Biopolymers (Block C.2)

6.4.2.1 Encoded Products

This information is required for biochemicals that are nucleic acids (repeating units of deoxyribonucleotides or ribonucleotides) and are subject to Schedule 1, 5 or 6 of the Regulations and for biopolymers that are nucleic acids and are subject to Schedule 3, 10 or 11 of the Regulations. This information must include the identification of the encoded products, if known.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture and that are subject to Schedule 1 or 3 of the Regulations.

6.4.2.2 Biological Activity

This information is required for biochemicals that are nucleic acids (repeating units of deoxyribonucleotides or ribonucleotides) and are subject to Schedule 1, 5 or 6 of the Regulations and for biopolymers that are nucleic acids and are subject to Schedule 3, 10 or 11 of the Regulations. This information must include a description of any known biological activity (e.g., antibiotic resistance) or adverse environmental or human health effects associated with the nucleic acid or with the encoded products, specified under item 5 of Schedule 2.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture and that are subject to Schedule 1 or 3 of the Regulations.

6.4.2.3 Catalytic Function

A description of all known catalytic functions is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture and that are subject to Schedule 1 of the Regulations.

6.4.2.4 Enzyme Commission Number and Name

The four-digit Enzyme Commission number, if available, and the enzyme's name are required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations.

Biochemicals that are enzymes should be named in accordance with the International Union of Biochemistry and Molecular Biology (IUBMB) or CAS nomenclature conventions. Group terms such as protease are not acceptable. The name must uniquely identify a single enzyme (e.g., subtilisin produced by *Bacillus subtilis*).

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture and that are subject to Schedule 1 of the Regulations.

Enzyme Commission numbers, as designated by the nomenclature committee of the IUBMB, are also commonly referred to as IUBMB numbers. The Enzyme Commission number is the source for internationally accepted enzyme nomenclature and classification systems.

The Enzyme Commission number is a four-figure set in which the first figure denotes one of the six main classes of catalytic substances based on the reaction catalyzed; the second and third figures indicate subclasses; and the fourth figure is the serial number of the catalytic substance in its subclass. The four-digit Enzyme Commission number is a unique number assigned to substances with catalytic activity. When enzymes are being notified, the most precise fourth-level Enzyme Commission number available must be obtained and submitted. For example, Enzyme Commission number 1.1.2 would not be acceptable for Mannitol dehydrogenase (cytochrome); the acceptable Enzyme Commission number for this substance is 1.1.2.2.

Enzyme Commission numbers can be obtained at https://www.qmul.ac.uk/sbcs/iubmb/enzyme/.

6.4.2.5 Substrate Specificity

This information is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. This information must include the known substrate specificity for each known catalytic function specified under item 7 of Schedule 2 of the Regulations.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture and that are subject to Schedule 1 of the Regulations.

6.4.2.6 Optimum pH and Temperature

This information is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. This information must include the optimum pH and temperature for the substrates specified under item 9 of Schedule 2 of the Regulations.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture and that are subject to Schedule 1 of the Regulations.

6.4.2.7 Catalytic Constants K_M and K_{cat}

This information is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. This information must include the catalytic constants K_M and K_{cat} and the conditions under which they were measured.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture and that are subject to Schedule 1 of the Regulations.

6.4.2.8 Cofactors

This information is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. This information must include the known cofactors necessary for enzymatic activity (e.g., NADPH, coenzyme Q).

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture and that are subject to Schedule 1 of the Regulations.

6.4.2.9 Enzymatic Activity

This information is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. This information must include the activity per unit weight of products and, if known, of end-use products.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture and that are subject to Schedule 1 of the Regulations.

6.5 Additional Information Requirements (part D)

When using Part D to list all attachments included, notifiers must check the appropriate box to indicate that the document provided is considered confidential (i.e., mark “Y” to indicate that the information provided is considered confidential or mark “N” to indicate that the information provided is not confidential). If the information provided is considered confidential, the notifier must provide, in the NSN, the supplementary information detailed in section 7.2 of this Guidance Document.

6.5.1 Other Agencies (Block D.1)

This information is required for all substances subject to any Schedules of the Regulations. This information must include:

a) any known instances where the manufacture or importation of the substance has been notified to other government agencies, either outside or within Canada, and the purpose of such notification;
b) if known, the identity of the agency, including the complete name, city and country where the agency is located; and

c) if known, the agency's file number, the outcome of the assessment and the risk management measures imposed by the agency.

For example, the Ontario Ministry of Labour may have been notified of the import of a new substance for use in an occupational setting, or an American supplier may have notified the US EPA under the Pre-Manufacture Notice (PMN) provisions of the *Toxic Substances Control Act*.

6.5.2 Other Requirements (Block D.2)

This information is required for substances subject to any Schedule of the Regulations. It must include a summary of all other information and test data in respect of the substance that are in the possession of the manufacturer or importer or to which they may reasonably be expected to have access and that permit the identification of hazards to the environment and human health and the degree of environmental and public exposure to the substance. The NS program considers all available information to inform its risk assessment, including, but not limited to, data from *in vitro* screening assays, mechanistic endpoints, toxicogenomics and other emerging technologies. Summaries must provide sufficient detail regarding methodology and results to permit the NS program to determine the relevance and quality of the information. The NS program may ask to see the full report after reviewing the summaries provided.

"In the possession of the manufacturer or importer" means the information in the company's offices in Canada if the NSN was submitted by a Canadian company or the information in the offices in the country where the notification originated if the NSN was submitted by a foreign company through a "Canadian Agent." The phrase "to which they may reasonably be expected to have access" means information in any of the company's offices worldwide or other locations where the notifier can access the information.

6.5.3 Other Requirements for Nanomaterials (Block D.3)

For nanomaterials, information in addition to the required technical information may be needed by the NS program to conduct an assessment. Information such as primary particle size and particle size distribution, agglomeration (aggregation) state, shape, surface area, surface functionalization, surface coating and surface charge should be submitted. This information is recommended for substances subject to any Schedule of the Regulations.

For water solubility and *in vitro* test for gene mutation in mammalian cells, alternative test protocols are recommended for nanomaterials. Refer to sections 6.3.1.3 and 6.3.3.5 of this Guidance Document.

6.5.4 Additional Information and Attachments (Block D.4)

In certain cases, information in addition to the required technical information may be needed by the NS program to conduct an assessment. Since these other information elements apply to a small subset of notified substances, they have not been included in

the Regulations. For example, when a substance is known to partition to soil and/or sediment, data from one toxicity test on a soil- or sediment-dwelling organism may be needed to conduct an assessment. It is also possible for the soil or sediment toxicity test to replace prescribed information requirements such as data from acute fish, daphnia or algae toxicity tests.

Additional data that may be needed under certain circumstances are described in Table 6-3. These descriptions are intended to alert notifiers to the potential need for generating additional data. If the notified substance meets any of the case(s) described in Table 6-3, notifiers are advised to submit a PNC request (see section 8.8) prior to generating the additional technical information in order to discuss the validity and relevance of each data element on a case-by-case basis.

Table 6-3 Cases Where Additional Technical Information May be Needed

Case	**Additional Technical Information[a] That May Be Needed**
Substances that are used as follows:	
As a polymer additive (> 10% wt.) Use is external and/or exposed to weathering (e.g., asphalt, epoxy coatings used for pipelines)	Leachability potential Soil toxicity Blooming potential Off-gassing potential Degradation/breakdown products Potential to enter water table
In saltwater environments	Marine toxicity Relative solubility in salt/fresh water
Substances with the following properties:	
Poorly soluble or insoluble in water and/or expected to have a large octanol/water partition coefficient	Slow-stir water solubility Bioconcentration factor Bioaccumulation factor Chronic aquatic toxicity Subchronic mammalian toxicity (toxicokinetics)
Predicted to fail ready biodegradation test criteria	Inherent biodegradation Subchronic mammalian toxicity (toxicokinetics)
Surface active	Surface tension Critical micelle concentration Dermal irritation and sensitization Dermal toxicity
Ionizable	Distribution coefficient (log D) Dissociation constant (pKa) Surface tension
Known to partition to soil and/or sediment	Benthic toxicity

	Soil toxicity Terrestrial toxicity
Biologically active (e.g., pharmaceuticals)	Chronic aquatic toxicity Subchronic mammalian toxicity/carcinogenicity (toxicokinetics) Metabolic breakdown products Relative bioavailability (dermal/oral)
Substances that are members of the following chemical class:	
Ozone depleting substances (e.g., halons, as defined in the Montreal Protocol)	Ozone depletion potential Global warming potential Inhalational mammalian toxicity (toxicokinetics)
Cationics	Mitigation of ecotoxicity to fish by humic acid
Potential endocrine disruptors	Mechanistic *in vitro* screening assay Amphibian metamorphosis Two-generation reproduction toxicity with endocrine screening
Confirmed or potential nanomaterials (see Appendix 10)	Particle size and size distribution, agglomeration (aggregation) state, shape, surface area, surface functionalization, surface coating, surface charge, etc; Release potential of the substance from a final product Soil toxicity Inhalational mammalian toxicity (including toxicokinetics) Genotoxicity (other than Ames test)
Phthalates or flame retardants or perfluorinated substances	Chronic aquatic toxicity Reproductive/developmental toxicity Subchronic mammalian toxicity (toxicokinetics) Mechanistic *in vitro* screening assay
Metals and metal compounds	Transformation/dissolution in aqueous media Subchronic mammalian toxicity (toxicokinetics) by appropriate route of exposure

	Skin sensitization Carcinogenicity
Enzymes	Amino acid sequences of native and mutated enzyme

[a]Refer to the Organisation for Economic Co-operation and Development (OECD) Guidelines for the Testing of Chemicals (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_72d77764-en) for internationally accepted standard test methods.

Additional information requirements refer to any information and data relevant to environmental and health hazard identification, such as:

a) experimental data (including negative results);
b) summaries of literature reviews;
c) results of searches from databases conducted by the notifier;
d) structure–activity relationship analyses performed on the substance or structurally related substances;
e) reports of adverse effects identified as a result of the use of the notified substance in an occupational setting;
f) results of studies of the risk to employees, customers, the public or the environment (e.g., environmental fate modelling) that may result from the use of the substance; and
g) toxicogenomic data.

Information about possible environmental benefits resulting from the manufacture or use of the notified substance may also be provided. If the benefit relates to the substitution for another substance, information in block A.15.6 of the NSN Form should be provided. Examples of such benefits include the following:

a) the substance is a “less toxic” substitute for an existing substance or technology;
b) the substance is recovered from a waste stream;
c) the manufacture or use of the substance will generate less waste than an existing substance; or
d) the substance may be recycled.

Any information provided as “additional information” may be provided in the language in which the information was originally prepared. The NS program requests that at least a summary of any additional information be provided in English or French.

6.6 Human and Environmental Exposure Information (Known and Anticipated) (Part E)

Part E of the NSN Form identifies all of the manufacture, import, use, and release information that is prescribed by the Regulations. This section also requests certain information that is not required by the Regulations, but that is highly relevant to help predict releases into the environment and potential human exposure to the new substance.

The information provided in this section is used directly in the risk assessment to evaluate potential exposure and release of the new substance throughout its main life cycle stages. This includes, but is not limited to, transportation, storage, manufacture, formulation/processing, equipment cleaning, use, and waste handling and disposal.

The risk assessment takes into consideration the exposure from the anticipated activities by the notifier as well as the potential activities of downstream processors and users of the substance. If specific information is not known by the notifier, such as in the case where the information relates to operations at sites controlled by others (e.g., manufacturing, formulation), responses may be provided to the extent known or ascertainable by contacting suppliers or customers. Exposure information provided in a US EPA PMN can also be provided to assist in the evaluation.

All parts of this section should be filled out as completely as possible if the information is known. In the absence of detailed information, the NS program typically adopts conservative estimates and modelling information to estimate potential exposure.

Footnotes on the NSN Form contain indications on the information that is required for each Schedule of the Regulations. Should any inconsistencies be found, the Regulations will prevail.

6.6.1 Anticipated Annual Manufacture, Import, and Export Quantities of the Notified Substance (Block E.1)

Report the amount of pure substance, not including solvents or other components if the substance is in a mixture. For consolidated notifications, report quantities for each substance.

6.6.1.1 Quantity of the Substance Manufactured, Imported and Exported (Block E.1.1)

This information is required for substances subject to any of the Schedules prescribed in the Regulations.

Complete the table according to the following instructions.

Quantity manufactured within Canada: The following information is required for substances that are subject to any Schedule of the Regulations. Indicate the anticipated annual quantity to be manufactured in Canada, if applicable. This information should include the amounts during the first 12 months and, if known, the expected maximum amount to be manufactured during any future 12-month period in kg/year. If there is none expected, indicate so.

Quantity imported into Canada: The following information is required for substances that are subject to any Schedule of the Regulations. Indicate the anticipated annual quantity to be imported into Canada, if applicable. This information should include the amounts during the first 12 months and, if known, the expected maximum amount to be

imported during any future 12-month period in kg/year. If there is none expected, indicate so.

Quantity for export: Indicate the anticipated annual quantities to be manufactured in Canada or imported into Canada for export, if applicable. This information should include the amounts during the first 12 months and, if known, the expected maximum amount to be exported during any future 12-month period in kg/year. If there is none expected, indicate so.

6.6.1.2 Canadian Sites of Greatest Quantity (Block E.1.2)

This information is required for chemicals subject to Schedule 5 or 6 and non-RRR polymers subject to Schedule 9, 10 or 11 of the Regulations. For contained site-limited intermediate substances subject to Schedule 1 or 3 of the Regulations, the single location of use is required.

Complete the table according to the following instructions.

Site: If known, identify the three sites (company names and site addresses) in Canada where the greatest quantity of the substance, manufactured or imported by the notifier, is anticipated to be used and/or processed.

Used or Processed: Identify whether the substance is used and/or processed at the site.

Quantity: Provide the estimated quantity used and/or processed at the site (in kg/year).

6.6.2 Uses Involving the Substance (Block E.2)

6.6.2.1 Description of Activities in Canada (Block E.2.1)

This information is required for substances subject to any of the Schedules prescribed in the Regulations. A description of all industrial, commercial, and consumer activities involving the substance in Canada (e.g., manufacture, import and distribution; industrial formulation, reformulation of a concentrate, commercial activity) should be provided, to the extent to which it is known or reasonably ascertainable. This should include the activities undertaken by the notifier and by downstream processors or users of the substance in Canada.

If the substance is imported into Canada, a description of the imported product(s) containing the notified substance (e.g., pure notified substance, intermediate product, end-use product) should be provided.

Industrial, commercial, and consumer activities can be defined as

- **Industrial**: The substance, or products containing the substance, will be used at the site of manufacturers or large-scale processors/users (e.g., textile dyeing, paint formulation, use of a curable resin to manufacture a product).
- **Commercial**: The substance, or products containing the substance, will be used by a commercial enterprise providing a consumer service (e.g., use by commercial dry cleaning establishments, use by painting contractors, use by roofers in commercial building construction).
- **Consumer**: The substance, or products containing the substance, will be used by private individuals (e.g., personal care products, automotive oil, dishwashing detergent).

6.6.2.2 Anticipated End-Uses, Functions and Concentration of the Substance (Part E.2.2)

The intent of this section is to describe how the substance is imported, and whether it is blended into intermediate products prior to incorporation into final end-use products. It is also intended to obtain information about the function and end-uses of the substance in products and anticipated products that contain it.

Provide the concentration (or range of concentrations) of the notified substance in the product(s) as imported or manufactured in Canada. This information is required for chemicals subject to Schedule 1, 4, 5 or 6 and non-RRR polymers subject to Schedule 3, 9, 10 or 11 of the Regulations.

Identify and describe each anticipated end-use products containing the new substance (e.g., architectural paint, hair shampoo, automotive lubricant). Indicate the function of the substance. The function is related to the inherent physical and chemical properties of the substance (e.g., degreaser, catalyst, plasticizer, UV absorber, fragrance). Identify if the end-use is an industrial, commercial and/or consumer activity. Indicate the concentration of the substance, if known and the percent of annual quantity. The percent of annual quantity is the percentage of total annual quantity imported or manufactured for each end-use (when adding the percentages for each end-use, it should equal 100%). In some cases, a substance may be used for several different uses and each of these should be reported. For example, an emollient in hand soap may also be used as a surfactant in automobile spray wax. This information is required for substances subject to any of the Schedules prescribed in the Regulations.

The following are some examples of functions and uses:

- an emollient in hand soaps
- a disperse dye carrier for finishing polyester fibers
- a cross-linking agent for epoxy-type coatings for metal surfaces
- a flame retardant for surface application on cotton apparel, textile home furnishings, and exterior canvas products
- a surfactant in automobile spray wax
- a colorant for paper and other cellulosic products

- a fiber-reactive dye for nylon carpeting and upholstery
- an antioxidant in fuel oils and lubricants

6.6.2.3 Historical and Other Likely End-Uses, Functions and Concentrations of the Substance (Block E.2.3)

The purpose of this section is to obtain information about the historical and other likely functions and end-uses for the new substance. Complete the table following the guidance in section 6.6.2.2. These uses and functions are not envisioned to be pursued by the notifier, but are known historically to exist in other jurisdictions or in the patent literature, or understood based on knowledge of the substance properties. This information is required for NDSL chemicals subject to Schedule 5, chemicals subject to Schedule 6, and polymers subject to Schedule 10 or 11 of the Regulations.

The NS program recommends that this information be provided to the greatest extent known, even if such uses are not expected to be pursued. For example, surfactants intended for use in industrial applications may also be suitable for use in personal care products. Detailed information of this kind will assist the NS program in determining the exposure characterization of the substance. Where only limited information is provided, exposure evaluations will be based on conservative estimates.

6.6.3 Human Exposure (Block E.3)

The purpose of this section is to obtain information about the potential for direct human exposure to the notified substance, including from the use of consumer products. If the notifier does not have specific information about the potential for human exposure, then descriptions can be based on information provided by downstream processors and users of the substance or on experience with similar substances. The notifier should provide all information requested, to the extent to which it is known or reasonably ascertainable. Where only limited information is provided, exposure evaluations will be based on conservative estimates.

6.6.3.1 Direct Human Exposure (Block E.3.1)

Describe the anticipated circumstances and degree of direct human exposure to the substance, including the concentration of the substance, the duration and frequency of exposure and the route of exposure (dermal, oral, inhalation).

Indicate if the substance is anticipated to be used in products intended for use by or for children. If yes, describe the types of products (e.g., shampoo, markers).

Describe any conditions of use or factors that may limit direct human exposure to the substance.

This information is required for chemicals subject to Schedule 5 or 6 and non-RRR polymers subject to Schedule 9, 10 or 11 of the Regulations.

6.6.3.2 Significant Public Exposure (Block E.3.2)

Indicate whether the public is anticipated to be significantly exposed to the substance in a product, taking into account factors including concentration of the substance, duration, frequency and circumstances of exposure (e.g., route of exposure) and factors that may limit direct human exposure. If not, provide information substantiating that the public is not anticipated to be significantly exposed.

This information is required for substances subject to Schedule 1, 3 or 10 and NDSL chemicals subject to Schedule 5 of the Regulations. Additional test data may be required prior to importing or manufacturing more than 50 000 kg/year depending on the assessment of this information (review sections 4.4.3.2 and 4.9.2.2 of this document).

6.6.4 Environmental Exposure (Block E.4)

6.6.4.1 Description of Operations (Industrial, Commercial and Consumer) (Block E.4.1)

This section focuses on the major life cycle steps where environmental release could occur, including the manufacturing, processing, commercial use, and consumer use operations involving the substance or products containing the substance. In many cases, these life cycle steps may involve multiple users of the substance, including separate manufacturers, blenders, and end-users. For example, for a surfactant used in metal working fluids, there may be surfactant manufacture, processing into metal working fluids, and use in industrial metal cutting operations.

In most cases, specific information relating to operations under the notifier's control will be available. Where specific information is not available, for example, in the case where operations are controlled by downstream processors or users of the substance descriptions can be based on available information and experience with similar substances. The notifier should provide all information requested, to the extent to which it is known or reasonably ascertainable. Where only limited information is provided, exposure evaluations will be based on conservative estimates.

Complete sections E.4.1A, E.4.1B and E.4.1C for the substance as applicable.

Manufacture and/or Processing of the Notified Substance in Canada (Block E.4.1A)

Processing the notified substance can include, for example, formulation or blending the substance.

For the description of operation and/or flow diagram, identify the major steps, focusing on waste streams and potential points of release of the substance during the operation and equipment cleaning.

If the same operation occurs at multiple sites and the processes differ significantly, or if there are multiple operations, the information can be reported by replicating the table.

Complete the table according to the following instructions.

Number of sites: Enter the number of sites where the substance is manufactured and/or processed.

Batch operations: All components are loaded into the vessel together or in a pre-defined sequence until the desired product is formed and subsequently discharged in a single batch. Processing of subsequent batches must wait until the current batch is finished.
In the table, provide the maximum quantity produced per batch, the maximum number of batches per day, and the maximum number of batches that are expected to be produced per month.

Continuous operations: Components are continuously charged into the vessel and the desired product is continuously formed and discharged. In the table, provide the maximum quantity produced per day, and the maximum expected number of days of operation per month.

Description of operation and/or flow diagram: Identify the major operational steps in the manufacture of the substance, focusing on waste streams and potential points of release of the substance. This should include a brief description or flow diagram of the main steps of the manufacturing process that identifies

- features such as process tanks, holding tanks and distillation towers;
- the points of entry of all components; and
- the points of release of the substance.

Procedures for cleaning: Provide a brief description of the methods used for cleaning the equipment, transportation lines, and vessels (e.g., vacuumed, washed with water, washed with organic solvents) and the maximum cleaning frequency (e.g., per month, after each batch).

This information is required for manufacture and/or processing of notified substances in Canada that are subject to any of the Schedules prescribed in the Regulations.

Industrial and commercial uses (Block E.4.1B)

Describe the industrial and/or commercial uses for the substance. Industrial uses include, for example, painting automotive parts, applying interior pipe coatings, lubricating equipment. Commercial uses include, for example, dry cleaning, car washes, automotive servicing.

To complete the remainder of the table, refer to instructions for Block E.4.1A.

This information is required for substances with industrial and/or commercial uses that are subject to any of the Schedules prescribed in the Regulations.

Consumer uses (Block E.4.1C)

Describe the consumer uses for the substance. Consumer uses include, for example, dishwashing, do-it-yourself automotive oil changing.
This information is required for substances with consumer uses that are subject to any of the Schedules prescribed in the Regulations.

6.6.4.2 Description of the Transportation and Storage Operations (Block E.4.2)

Cleaning of transport and storage vessels is historically associated with significant releases to the environment. For this reason, the exposure assessment conducted for each new substance pays particular attention to the vessels used for transporting and storing the substance.

In most cases, specific information relating to operations under the notifier's control will be available. Where specific information is not available, for example, in the case where operations are controlled by downstream processors or users of the substance, descriptions can be based on available information and experience with similar substances. The notifier should provide all information requested to the extent to which it is known or reasonably ascertainable. Where only limited information is provided, exposure evaluations will be based on conservative estimates.

This information is required for chemicals subject to Schedule 1, 5 or 6 and polymers subject to Schedule 3, 10 or 11 of the Regulations.

6.6.4.3 Limiting Environmental Exposure (Block E.4.3)

Describe any factors that may limit environmental exposure to the substance (e.g., incineration, chemical treatment, pollution prevention practices, recycling, existing regulatory requirements) including on-site treatment. This information is required for NDSL chemicals subject to Schedule 5, chemicals subject to Schedule 6, and polymers subject to Schedule 10 or 11 of the Regulations.

Describe the methods recommended for destruction or disposal of the substance. This information is required for chemicals subject to Schedule 1, 5 or 6, and polymers subject to Schedule 3, 10 or 11 of the Regulations.

Recycling activities include reclamation of useful chemical components from wastes that would otherwise be released as air emissions, water discharges or land releases during manufacture, process or use. All descriptions may be quantitative or qualitative.

6.6.4.4 Handling Waste Containing the Substance (Block E.4.4)

The information requested in this section is provided to describe and quantify potential releases of the substance and waste to the environment. This should include

information from each industrial and commercial operation and consumer use in Canada.

In many cases, releases may occur at separate life cycle steps involving different users of the substance, including separate manufacturers, blenders, and end-users. For example, for a surfactant used in metal working fluids, there may be surfactant manufacture, processing into metal working fluids, and use in industrial metal cutting operations.

In most cases, specific information relating to operations under the notifier's control will be available. Where specific information is not available, for example, in the case where operations are controlled by downstream processors or users of the substance, descriptions can be based on available information and experience with similar substances. The notifier should provide all information requested to the extent to which it is known or reasonably ascertainable. Where only limited information is provided, exposure evaluations will be based on conservative estimates.

Information about the releases of the substance from each industrial and commercial operations and consumer use in Canada should be provided. Releases generated from operational processes and from cleaning equipment, transport and storage vessels should be included. This information is required for chemicals subject to Schedule 1, 5 or 6, and polymers subject to Schedule 3, 10 or 11 of the Regulations.

Amongst the information requested, the component(s) of the environment into which the substance is anticipated to be released (e.g., receiving body of water, agricultural land, air) should be provided. This information is required for chemicals subject to Schedule 1, 5 or 6 and polymers subject to Schedule 3 or 11 of the Regulations.

If there are multiple sources of release which differ significantly, the information can be reported by replicating the table.

6.6.4.5 High Release to the Aquatic Environment (Block E.4.5)

This information is required for NDSL chemicals subject to Schedule 5 and polymers subject to Schedule 10 of the Regulations. Additional test data may be required prior to importing or manufacturing more than 50 000 kg/year depending on the assessment of this information (review sections 4.4.3.1 and 4.9.2.1 of this document).

Indicate whether the substance is anticipated to be released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment (i.e. the substance is expected to lead to high release). If the release is less than or equal to 3 kg per day, per site, provide the data substantiating the quantity

released. Some detailed guidance on what is required and how to calculate the high release estimate is provided in the next section.

6.6.5 High Release Calculation

In general, to calculate the daily release to the aquatic environment averaged monthly ($DR_{ave\ mo}$) after wastewater treatment, the following formula can be applied for each site.

$$\mathbf{DR_{ave\ mo} = RDM \times QR \times (1\text{-}RE)/30.417}$$

Where:

RDM = number of *release days* per month

QR = quantity released on *release days*

RE = wastewater treatment removal efficiency

30.417 = the average number of days in a month

"*Release day*" is typically assumed to involve one release event, but it can involve more. For example, if the notifier or downstream user releases 5 kg of the notified substance to the municipal treatment plant in the morning and another 3 kg in the afternoon, then the "*release day*" would involve the sum of those quantities per day, or in this case the quantity released (QR) on the release day would be 8 kg/day.

The average number of days in a month is taken as 30.417 days, which is derived from 365 ÷ 12. This value is used to account for "averaged monthly" releases.

6.6.5.1 Estimating the Number of Release Days per Month

The number of release days per month (RDM) is a function of operations and can vary throughout the year at any site. The following scenarios provide some examples:

<u>Releases occur 7 days per week, throughout the year</u>

If releases occurred every day all year, then the RDM would equate to the typical number of days in a month, i.e., 30.417 days/month.

<u>Releases occur 5 days per week:</u>

If releases typically occurred 5 days per week but operations involving the substance only occurred 200 days of the year, to obtain the RDM, take the worst-case month in the year (i.e., every week) and multiply this by the average number of weeks per month i.e., (4.345 weeks/month) x (5 releases/week) to obtain the RDM of 22 days/month.

Note: 30.417 days/month ÷ 7 days/week = 4.345 weeks/month

<u>Releases occur only during one week in the year:</u>

For example, if facility operations release the new substance on only 5 consecutive days in the year, then this would be used to represent the worst-case month and the RDM would be 5 days/month.

Releases occur once or twice a month throughout the year:

If the facility releases the notified substance either once or twice every month throughout the year, then the RDM would reflect the worst-case month and be set at 2 days/month.

6.6.5.2 Determining the Quantity Released on Release Days

The QR can be determined for continuous or periodic releases. If it is known that a certain quantity of the substance is lost on each release day, then it can be applied directly as the QR. If neither of the scenarios below apply, supporting evidence must be provided to support the QR.

Continuous daily release

If the releases to a wastewater treatment plant are continuous and occur on a daily basis throughout the year, then the QR can be determined based on the annual quantity along with an estimated or measured fraction lost during the operations, e.g., from equipment cleaning and/or operational losses. For example, if the annual quantity of the substance is 20 000 kg/year at one site over 250 days and it is known or estimated that 3% is lost during operations, then the average quantity released on release days would be as follows:

Example 1: QR = 20 000 kg/year x 0.03 ÷ 250 days/year

= 2.4 kg/day

Therefore, the QR is 2.4 kg/day.

Periodic release

If the release is associated with periodic cleaning of transportation lines and mixing vessels after several batch runs, then one must consider the specific release quantity during that particular process. For example, if the total quantity of the substance in any given batch is 2 000 kg, and the residual level of the substance in the equipment prior to cleaning is 2.5%, and the cleaning operations take place on one day, then the quantity of substance released on the release day is estimated as follows:

Example 2: QR = 2 000 kg/batch x 0.025 ÷ 1 day

= 50 kg/day

Therefore, the QR is 50 kg/day.

6.6.5.3 Determining the Wastewater Treatment Removal Efficiency

The removal efficiency (RE) of the substance following wastewater treatment is an important part of the equation supporting the high release estimate. There are a variety of ways to determine the RE. For instance, the RE can be determined by monitoring actual influent and effluent from a wastewater treatment facility. In such cases, a description of the monitoring activities must be provided. In most cases, however, it is expected that the RE will be estimated. Estimates can be based on physical and chemical properties and professional judgement or based on computer simulated modelling. In either case, a description of the process or supporting evidence must be provided.

For example, for a particular structure and physical chemical properties, the wastewater treatment RE estimated from the US EPA computer estimation program EPI Suite™ is determined to be 82%. This value can be taken as the RE.

6.6.5.4 Examples of Calculations

Based on the above scenarios, the following $DR_{ave\ mo}$ examples are derived.

$DR_{ave\ mo}$ = RDM x QR x (1-RE)/30.417

Example 1
RDM = 22 days/month
QR = 2.4 kg/day
RE = 82%
$DR_{ave\ mo}$ = (22 days/month) x (2.4 kg/day) x (1-0.82)/30.417 days/month

Therefore, the $DR_{ave\ mo}$ = 0.34 kg/day per site, averaged monthly and after wastewater treatment and is not expected to lead to high release.

Example 2

RDM = 2 days/month
QR = 50 kg/day
RE = 82%
$DR_{ave\ mo}$ = (2 days/month) x (50 kg/day) x (1-0.82)/30.417 days/month

Therefore, the $DR_{ave\ mo}$ = 0.59 kg/day per site, averaged monthly and after wastewater treatment and is not expected to lead to high release.

SECTION 7 — CONFIDENTIAL INFORMATION

Under section 313 of the *Canadian Environmental Protection Act, 1999* (the Act), any notifier who provides information to the government may, at the same time, submit a written request that the information be treated as confidential. This feature ensures that genuine Confidential Business Information (CBI) is protected from public disclosure. The degree of protection given to information claimed to be confidential will be consistent with sections 314–321 of the Act and the provisions of the *Access to Information Act*.

7.1 Claiming Confidentiality

For information to be treated as confidential, the request must be submitted with the New Substances Notification (NSN) and must:

a) indicate which particular information is confidential using the appropriate field in the NSN Form (specific information provided in attachments to the NSN Form can also be put in brackets, **[ ]**); and
b) include all supplemental information (detailed in section 7.2).

7.2 Information Supporting a Confidentiality Claim

The New Substances (NS) program aims to obtain a balance between protecting CBI while ensuring some degree of transparency. General confidentiality claims and claims for substance identity confidentiality in an NSN must be accompanied by the supplementary information detailed in sections 7.2.1 and 7.2.2. Notifiers will be advised if their request for confidentiality is incomplete and given an opportunity to review and provide additional substantiation for their claim. Not providing the additional substantiation could lead to the unwanted publication of the notified information. Alternatively, the notifier may choose to withdraw the confidentiality claim.

7.2.1 General Confidentiality Claims

Claims for confidentiality should only be made when the submitted information is truly confidential, such as when it is a trade secret or where its disclosure could negatively impact the competitive position of the submitter. To reduce the scope of confidentiality requests and focus on what is truly confidential, a request for confidentiality must indicate which specific information or data should be treated as confidential. A justification must be provided to any request for confidentiality describing the nature of the confidentiality. The justification should be selected from the following criteria:

a) it is a trade secret of the submitter;
b) it is information of a financial, commercial, scientific or technical nature that is treated consistently in a confidential manner by the submitter;
c) its disclosure could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of the submitter; or

d) its disclosure could reasonably be expected to interfere with contractual or other negotiations of the submitter.

7.2.1.1 Information Generally Not Expected to Be Confidential

Although submitters may claim any information they submit as confidential, certain types of information of value for risk assessment of substances and for other purposes related to the protection of human health and the environment are generally not expected to be confidential. Release of this information is seen as desirable to promote transparency.

There is consensus within Organisation for Economic Co-operation and Development (OECD) member states that no restriction needs to be put on the exchange of information described below between governments or on the disclosure of such information to the public.

The following list identifies the kinds of information that would not be expected to be confidential, although it is understood that there will be exceptions. It is not restrictive and is based on the *Recommendation of the Council concerning the OECD List of Non-Confidential Data on Chemicals 26 July 1983 - C(83)98/FINAL* available via the OECD website at https://legalinstruments.oecd.org/en/instruments/32.

a) Trade name(s) or name(s) commonly used;
b) General information about uses (the uses need to be described only broadly: closed or open system, agriculture, domestic use, etc.);
c) Safe handling precautions to be observed in the manufacture, storage, transport and use of the substance;
d) Recommended methods for disposal and elimination;
e) Safety measures in case of an accident;
f) Physical and chemical information, with the exception of data revealing the substance identity (e.g., spectra). If the physical and chemical information make it possible to deduce the substance identity, non-confidential ranges of values can be identified; and
g) Summaries of health, safety, and environmental data including precise figures and interpretations. In cases where the study is claimed confidential, the submitter of the health, safety, and environmental study has the option of preparing a non-confidential summary. If no summary is provided, Environment and Climate Change Canada and Health Canada will prepare one following the OECD harmonized template format: http://www.oecd.org/ehs/templates/.

7.2.2 Confidential Substance Identity Claims

When the identity of a substance is claimed confidential, the procedures for generating a masked name are prescribed in the *Masked Name Regulations*. These procedures

are further elaborated in Appendix 5 of this Guidance. These procedures are in place to maintain a balance between protecting CBI and ensuring some degree of transparency.

Masking may be accomplished by disguising single distinctive elements of the explicit chemical name of the substance, while retaining the generic identity/molecular structure of the substance. In most cases, masking a single distinctive element of the explicit chemical name of the substance would be sufficient, although masking multiple elements of the substance is also accepted when needed, with supporting justifications.

The explicit chemical name of the substance is the name established in accordance with the current chemical nomenclature rules of the International Union of Pure and Applied Chemistry (IUPAC) or Chemical Abstracts Service (CAS).The explicit name is required when submitting an NSN Form, a Domestic Substances List (DSL) Nomination Form or a Non-domestic Substances List (NDSL) Nomination Form. Please note that a substance will not be eligible for addition to the Domestic Substances List until an acceptable masked name is received (see section 10.2 for eligibility requirements).

Masked names will be reviewed upon submission. If the claim for confidentiality of the explicit chemical name is acceptable, the proposed masked name will be evaluated to determine whether or not it is consistent with the *Masked Name Regulations.* If a masked name is considered unacceptable, the NS program will communicate that decision to the notifier and an alternative name will be requested. If a consensus is not reached, the NS program will publish a masked name that, in its opinion, will respect the confidentiality claim of the company while reflecting the generic molecular structure of the substance. Review of the masked name is separate from the review of the NSN and will not affect the assessment period for the substance. Note that there are fees associated with a masked name application (see fee table on the NSN fees webpage[27]).

Publication of an acceptable masked name is required under section 88 of the Act if publication of the actual identity of a substance would result in the release of CBI. Therefore, when claiming confidentiality for substance identity, the notifier should, in addition to the certification described in section 7.2.1 above, provide the following information:

a) a proposed masked name developed in accordance with the prescribed masking procedures (see Appendix 5);
b) justification for additional masking, i.e. disguising more than one distinctive element (see Appendix 5); and
c) the following information:
    i) the detrimental effects on the competitive position of the notifier's company that would result from the identity of the substance appearing on the DSL or in any other publication;
    ii) the manner in which a competitor could use the identity of the substance;

[27] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

iii) an indication of whether the identity of the substance has been kept confidential to the extent that competitors do not know it is being manufactured, imported or used;
iv) an indication of whether the substance has been patented and, consequently, disclosed through the patent;
v) an indication of whether it is public knowledge (e.g., publications in technical journals or trade publications) that the substance is being manufactured, imported or used;
vi) the measures that have been taken to prevent undesired disclosure of the substance identity and the extent of any disclosures to date;
vii) an indication of whether the substance is, or will be, in an effluent, emission or waste entering the environment;
viii) an indication of whether the substance is, or will be, in a product available to the public, and whether the substance can be identified by analysis of the product;
ix) the purpose for which the substance is being, or will be, manufactured, imported or used; and
x) an indication, to the best of the notifier's knowledge, of whether the NS program, another federal agency, a provincial or territorial agency or the agency of a foreign government has ever made a determination that this substance 1) has an immediate or long-term effect on the environment; 2) constitutes, or may constitute, a danger to the environment; or 3) constitutes, or may constitute, a danger to human life or health (if such a determination has been made, details should be provided).

An acceptable masked name disguises the explicit chemical name as described above. As such, replacing components of the explicit chemical name with synonyms and then masking the synonyms will not be accepted.

Changing the order of components of the explicit chemical name of a polymer

Generally, it may be acceptable to change the order of monomers and reactants in the explicit chemical name of a polymer before masking. However, the first element of the name may not be moved. Furthermore, a written statement substantiating the need for moving the monomers and reactants will be required, together with a listing of the new position of each of the moved monomers and reactants with associated chemical names and structure diagrams.

Masking a pre-polymer

A pre-polymer that is conserved as part of the explicit chemical name is considered a single reactant for naming purposes, and thus cannot be broken up into its constituents. As a result, if the name of a pre-polymer is conserved in the explicit name of a polymer, then the pre-polymer chemical name must be equally conserved in the masked name. Structural components of the pre-polymer name can still be masked in accordance with the provisions of the *Masked Name Regulations*, just as they can be for single distinctive elements of the polymer explicit chemical name as a whole.

Duration of confidentiality claims for substance identity

To help increase awareness of the substances in the Canadian market, confidentiality claims for substance identity will be reviewed after a period of 10 years. Before this period expires, the NS program will make reasonable attempts to contact the notifier. A minimum of 30 days' notice before the expiry date will be provided to the notifier to update their claim if they wish the substance identity to remain confidential for an additional period of 10 years. To update a claim, notifiers need to follow the instructions described above in this section.

7.2.3 Certain Purposes for Which Information May Be Disclosed

There may be instances where the Government of Canada would wish to release certain confidential information publicly. These would include, but not be limited to, situations where it is in the interest of public health, public safety or the protection of the environment or when it is necessary for the purposes of the administration or enforcement of the Act.

In these situations, a review will be done to determine whether certain information claimed as confidential could be released to promote transparency or because it is in the best interest of Canadians. Reasonable effort will be made to contact the submitter of the information who will be asked to provide additional information to substantiate their original claim.

Under section 316 of the Act, information may be disclosed:

a) with the written consent of the person who provided it or on whose behalf it was provided;
b) as may be necessary for the purposes of the administration or enforcement of this Act;
c) under an agreement or arrangement between the Government of Canada or any of its institutions and any other government in Canada, the government of a foreign state or an international organization or any of its institutions, or between the Minister and any other minister of the Crown in right of Canada, where
    i. the purpose of the agreement or arrangement is the administration or enforcement of a law, and
    ii. the government, international organization, institution or other minister undertakes to keep the information confidential;
d) under an agreement or arrangement between the Government of Canada and the government of a foreign state or an international organization, where the government or organization undertakes to keep the information confidential; or
e) to a physician or prescribed medical professional who requests the information for the purpose of making a medical diagnosis of, or rendering medical treatment to, a person in an emergency.

7.3 Determining Presence of Confidential Substances on Lists

Substances listed confidentially on the DSL or NDSL are published with Confidential Substance Identity Numbers using masked identities that are named in a manner prescribed by the *Masked Name Regulations* as specified above. Any notifier who intends to manufacture or import a substance that he or she believes to be confidentially listed on the either of these lists may seek confirmation from the NS program. The NS program will respond to such an inquiry only if the notifier provides the NS program with a Notice of *Bona Fide* Intent to Manufacture or Import the substance. For more information about this, see section 2.3.1.

SECTION 8 — RECOMMENDED TEST PROTOCOLS AND ALTERNATIVE APPROACHES

8.1 Test Protocols

8.1.1 Organisation for Economic Co-operation and Development Test Guidelines

Subsection 15(1) of the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) states that the conditions to be met and the test procedures to be followed in developing the required test data for a substance must be consistent with the conditions and procedures set out in the Organisation for Economic Co-operation and Development (OECD) Guidelines for the Testing of Chemicals (the OECD Test Guidelines (TGs)) that are current at the time the test data are developed. The OECD TGs are set out in Annex 1 of the OECD *Decision of the Council Concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, adopted by the OECD on May 12, 1981 (https://legalinstruments.oecd.org/en/instruments/263).

The appropriateness of the OECD TGs method for the substance must be determined, and any necessary deviations must be reported and explained. The OECD TGs are not intended to serve as rigid test procedures appropriate for all substances; rather, they allow flexibility for expert judgement and adjustments to new developments.

8.2 Accepted Test Methods

Examples of test methods, based on the OECD TGs, recommended by the New Substances (NS) program for the generation of physico-chemical, toxicity and ecotoxicity data are provided in Tables 8-1 to 8-4 below. The acceptability of these test methods depends on the applicability of the methods to the substance under investigation. Sources of test methods listed in Tables 8-1 to 8-4 are given in section 8.6 of this Guidance Document.

Table 8-1 Physico-chemical Test Methods (Chemicals)

Data requirement	Schedules	Test method
Melting point	5, 6	OECD TG[a] 102
Boiling point	5, 6	OECD TG 103
Density	5, 6	OECD TG 109
Vapour pressure	5, 6	OECD TG 104
Water solubility	5, 6	OECD TG 105
Octanol/water partition coefficient	5, 6	OECD TG 107 or 117
IR,[b] UV,[c] mass or NMR[d] spectrum	6	As appropriate
Adsorption–desorption	6 and high release (s. 7(2) of the Regulations)	OECD TGs 106, 121 as appropriate
Hydrolysis rate as a function of pH	6 and high release (s. 7(2) of the Regulations)	OECD TG 111

[a]OECD TG – Organisation for Economic Co-operation and Development Test Guideline
[b]IR – Infrared
[c]UV – Ultraviolet
[d]NMR – Nuclear Magnetic Resonance

Table 8-2 Physico-chemical Test Methods (Polymers)

Data requirement	Schedules	Test method
Number average molecular weight	3, 9, 10, 11	As appropriate (e.g., OECD TG[a] 118)
Residual constituents with molecular weight < 500 daltons and < 1 000 daltons	3, 9, 10, 11	As appropriate (e.g., OECD TG 119)
Water extractability	10, 11	OECD TG 120
Hydrolysis rate as a function of pH	10, 11	OECD TG 111
Octanol/water partition coefficient	10, 11	OECD TG 117

[a]OECD TG – Organisation for Economic Co-operation and Development Test Guideline

Table 8-3 Toxicological Test Methods (Chemicals and Polymers)

Data requirement	Schedules	Test method
Acute mammalian toxicity	5, 6, 10, 11	OECD TGs[a] 402, 403, 420, 423, 425, 436
Skin irritation	6, 11	OECD TG 404, 430, 431, 439 ; see also section 6.3.3.2
Skin sensitization	6, 11	OECD TGs 406, 429, 442 (A-E)
Repeated-dose toxicity	6, 11 and high release (ss. 7(2), 7(3), 11(2) and 11(3) of the Regulations)	OECD TGs 407, 408, 409, 410, 412, 413, 422
Genotoxicity	5, 6, 11 and high release (ss. 7(3), 11(2) and 11(3) of the Regulations)	OECD TGs 471, 473, 474, 475, 476,[b] 487,[b] 488, 489

[a]OECD TG – Organisation for Economic Co-operation and Development Test Guideline
[b]Tests recommended for *in vitro* genotoxicity testing of nanomaterials

Table 8-4 Ecotoxicological Test Methods (Chemicals and Polymers)

Data requirement	Schedules	Test method
Acute fish toxicity	5, 6, 10, 11	OECD TG[a] 203, Environment Canada Biological Test Methods EPS1/RM/9 and EPS1/RM/13
Acute *Daphnia* toxicity	5, 6, 10, 11	OECD TG 202, Environment Canada Biological Test Method EPS1/RM/11
Algae toxicity	5, 6, 10, 11	OECD TG 201, Environment Canada Biological Test Method EPS1/RM/25
Ready biodegradability	5, 6, 11	OECD TG 301

[a]OECD TG – Organisation for Economic Co-operation and Development Test Guideline

8.3 Test Data Report

The notifier is obliged to submit a test report with sufficient information to allow the NS program to perform a thorough assessment and evaluation of the quality of these studies and their results. When submitting data to fulfill a prescribed information requirement, the full study must be provided, including the following information:

- identification of the test guideline and methodology employed;
- identification of the test substance, purity of the test substance, and its full composition (see section 6.2.25);
- reference methods, standards and controls employed;
- name and address of the test facility and the name of the person responsible for the study;
- dates on which the study was initiated and completed;
- raw data;
- deviations from the test protocol;
- analytical details, including sample preparation and instrument settings; and
- a presentation of results, calculations and statistical methods employed.

8.3.1 Good Laboratory Practice

Subsection 15(2) of the Regulations states that the laboratory practices to be followed in developing data for the following tests must comply with the practices set out in the "Principles of Good Laboratory Practice (GLP)" that are current at the time the test data are developed. The principles are set out in Annex 2 of the OECD *Decision of the Council Concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, adopted by the OECD on May 12, 1981 (https://legalinstruments.oecd.org/en/instruments/263):

a) acute mammalian toxicity tests;
b) repeated-dose mammalian toxicity tests;
c) genotoxicity tests;
d) tests to assess skin irritation;
e) skin sensitization tests;
f) acute fish, *Daphnia* or algae toxicity tests; and
g) biodegradation tests.

If any of the tests mentioned above were commenced or completed before the day on which the Regulations came into force (i.e., October 31, 2005), the laboratory practices used must be consistent with the practices set out in the "Principles of GLP."

The "Principles of GLP" are intended to promote the quality and validity of test data and to establish a basis for mutual acceptance of data among jurisdictions at the international level. They cover the organizational processes and conditions under which studies are planned, performed, monitored, recorded and reported.

The OECD has developed a series of decisions and guidelines relating to GLP. Documents are available via the OECD website at https://www.oecd.org/env/ehs/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm.

To be GLP-compliant, the final test report must include the Chemical Abstracts Service Registry Number (CAS registry number), name or trade name and the purity of the tested substance. The following information must also be provided:

a) the name, title and dated signature of the Study Director;
b) a GLP Compliance Statement from the Study Director;
c) the name, title and dated signature of the Principal Investigator;
d) the name, title and dated signature of the Quality Assurance Program;
e) Quality Assurance Statements from the Quality Assurance Program; and
f) dates and explanations of Quality Assurance Audits, including in-life audits.

Required studies submitted that are not compliant with GLP or do not contain the above-mentioned items will not be accepted, and the assessment period will not start until the appropriate and acceptable information has been provided.

Note that for studies of physico-chemical properties, GLP compliance is not mandatory.

8.3.2 Accreditation of Laboratories

If the test data submitted are from an accredited facility, then the accreditation should be stated and identified.

8.4 Alternative Approaches

Information in support of a New Substances Notification (NSN) may also be obtained from alternative test protocols or from calculation or estimation methods. These alternative approaches will be acceptable when, in the opinion of the NS program, they are determined to provide a scientifically valid measure of the endpoint under investigation that is deemed sufficient for the purposes of the risk assessment.

Requests for waivers of information are not required when submitting information from an acceptable alternative approach.

8.4.1 Alternative Test Protocols

Alternative protocols include other domestic or internationally recognized protocols, e.g., test methods developed or recognized by the NS program, the International Organization for Standardization (ISO), the American Society for Testing and Materials (ASTM), the United States *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) and the United States *Toxic Substances Control Act* (TSCA). In addition, protocols developed by individual companies or associations may also be acceptable, including,

but not limited to, protocols for *in vitro* screening assays, mechanistic endpoints, toxicogenomics and other emerging technologies. The protocol used by the notifier must be clearly referenced and described in sufficient detail to permit evaluation.

The alternative protocol must provide the desired data to a degree of accuracy acceptable to the NS program and must be described by the notifier in sufficient detail to allow an evaluation of the procedure and results. The NS program assesses whether the alternative protocol is consistent with the relevant OECD guideline (see section 8.1.1) and ensures the data was produced with a degree of accuracy acceptable to the program so that proper evaluations can be conducted.

The description of the alternative protocol should include, but not be limited to, a detailed description of the test principles and design, the methodology and controls used, validation studies of the accuracy and variability of the test method in comparison with the prescribed method, and any references to the protocol in the scientific or technical literature. The notifier should submit a test report with sufficient information to allow the NS program to perform a thorough assessment and evaluation of the quality of these studies and their results (see section 8.3).

A properly conducted human repeat insult patch test (positive or negative response) may be an acceptable alternative to animal testing for skin irritation or skin sensitization. The concentration of substance used in the test will be a critical factor in determining the acceptability of this information. Well-documented human use reports may also be an acceptable alternative to the prescribed test protocols for toxicological endpoints, especially skin irritation or skin sensitization tests (for positive responses only). The human use experience must be well-described and give particular emphasis to quantifying the exposure (concentration, duration, frequency) as accurately as possible. Anecdotal information from persons handling or exposed to the substance is not an acceptable substitute for performing a prescribed test.

8.4.2 Reduction, Refinement and Replacement

The NS program supports the principles of the Reduction, Refinement and Replacement approach to the use of alternative test protocols for minimizing unnecessary and avoidable animal use and suffering, where the quality of the information generated to conduct a risk assessment is not compromised. The method must have been satisfactorily validated in terms of scientific rigour, reproducibility and predictability.

An alternative that would reflect the reduction approach is one in which the number of animals needed to assess a particular endpoint can be decreased without compromising the scientific value of the test. Examples of reduction alternatives already accepted by international regulatory agencies include the updated OECD TGs for acute toxicity (OECD TGs 420, 423 and 425) and skin sensitization (OECD TG 429).

Refinement alternatives are aimed at reducing the distress or discomfort experienced by laboratory animals, during and following testing, by improving the design or efficiency of the test. Some examples include eliminating unnecessary handling and restraint of animals, availability of veterinary assistance, provisions for continual monitoring of health status and early termination of animals suffering undue pain or discomfort.

A replacement alternative is one that does not involve the use of a living animal. These alternatives include the use of validated computer-based models, physico-chemical information (e.g., information about pH to assess irritation potential), lower (e.g., invertebrate) organisms and *in vitro* tests on mammalian tissues and cell cultures.

8.4.3 Use of Surrogate Data

Read-across is an approach where an experimentally derived endpoint from one substance (called a surrogate or analogue substance) is used to predict the same endpoint for another substance that is considered to be similar with respect to that endpoint. The general principle of read-across is that substances which are similar in one or many aspects should also be similar in other aspects, such as physical, chemical, mammalian toxicological and ecotoxicological properties.

Read-across is acceptable when, in the opinion of the NS program, the data on the surrogate are as suited as, or better suited than, the data on the notified substance for measuring the endpoint under investigation. This approach can be used to fulfill a data requirement prescribed by the Regulations for which experimental data or study information is not available. However, it is important to note that a single surrogate substance may not be appropriate to fulfill all the data endpoints of a notified substance.

Supporting read-across information may be qualitative (e.g., the substance is mutagenic) or quantitative (e.g., median effective concentration (EC_{50})).

8.4.3.1 Justification for Using Surrogate Data

Any surrogate data submitted in lieu of experimental data on the notified substance must be supported by a scientific rationale justifying the selection of the surrogate substance and use of the read-across approach. In addition to the written rationale, a table with a side-by-side comparison of the notified and surrogate substance(s) is recommended (see section 8.4.3.3). In the justification, the following information should be provided for both notified and surrogate substances:

a) Identification information, including but not limited to the structural formula, molecular weight and functional group(s);
b) Physico-chemical and environmental fate data; and

For ecotoxicological and mammalian toxicological endpoints, in addition to water solubility and octanol/water partition coefficient comparisons, including but not limited to the following:

- mode of action;

- mechanism of action;
- bioavailability;
- reactivity;
- toxicokinetics;
- metabolic pathways and products; and
- degradation pathways and products.

The structural formula should be presented graphically. It should be detailed and the key structural elements or functional groups that are likely to affect a particular endpoint should be identified. Both structural similarities and differences between the substances should be considered and discussed.

For ecotoxicological and mammalian toxicological endpoints, confidence in surrogate data may be strengthened by showing that the notified and surrogate substances fit into a certain chemical group which has a pattern of potency or toxicological similarity across the group.

When surrogate data is being used to fulfill a regulatory requirement, full test reports for the studies and their results must be provided, including elements described in section 8.3 of this Guidance Document. The NS program recommends that full test reports for any other studies used in the comparison be provided. If available, an assessment of the reliability of the study results should also be provided.

If literature papers are referenced, a copy of each paper must be provided. Reviews by other regulatory agencies should be provided, if available.

Quantitative Structure–Activity Relationship (QSAR) estimates may be used to support the comparison of the notified and surrogate substances in a read-across approach, especially if the validity of QSAR estimate can be demonstrated (see section 8.4.4).

8.4.3.2 Additional Justification Requirements for Certain Substance Categories

The justification for the substance categories described below should include, but not be limited to, a comparison of the following additional points for both notified and surrogate substances:

Polymers

- molecular weight information (i.e., Gel Permeation/Size-exclusion Chromatography (GPC/SEC) chromatograms, polydispersity, number average molecular weight (M_n), weight average molecular weight (M_w), weight percent < 500 and < 1 000 daltons);
- monomer composition and initial starting concentrations of monomers used to synthesize the polymers;
- concentrations or amounts of any residual or excess monomers;

- the presence of any reactive functional groups, and any associated functional group equivalent weight (FGEW) calculations (see section 3.3.1.8); and
- reaction scheme of the polymers.

Unknown or Variable composition Complex reaction products or Biological materials (UVCBs)

- composition (representative structures and ratios);
- toxicity of major components; and
- starting materials and reaction conditions.

Inorganic chemicals

- crystal structure or 3-dimensional data;
- metal moiety and dissolution rate;
- ionic state; and
- stability.

Biochemicals and biopolymers (e.g., enzymes)

- primary structure (amino acid sequence) aligned with the notified substance to highlight differences; and
- enzyme-specific properties (e.g., catalytic constant K_M and K_{cat}, optimum pH and temperature; see section 6.4.2).

The factors considered for the acceptance of any potential surrogate for the substance categories described above may be complex; so notifiers are encouraged to submit a Pre-notification Consultation (PNC) request (see section 8.8).

8.4.3.3 Comparison Table

To facilitate the comparison of the notified and surrogate substances, it is recommended that their data be placed in a table similar to that shown below. If multiple surrogates are used, they can be arranged in multiple columns in a suitable order (e.g., according to molecular weight) to show a trend or progression for a target endpoint across the group. The cells in the table should also indicate whether the data are unavailable and, if possible, reliability of the study results.

These are general tables covering some sample endpoints; they are not meant to be an exhaustive list of all possible endpoints. Since the use of the read-across approach is endpoint-specific, all of the endpoints for which a potential surrogate is being submitted for consideration must be clearly indicated.

Table 8-5 Comparison Table of the Notified and Surrogate Substances

Parameter	Notified substance	Surrogate substance

Identification Information:		
CAS registry number[a]		
Chemical name		
Structural formula (image)		
Molecular weight (g/mol)		
Similarity indices (e.g., Tanimoto, Dice)		
Relevant functional groups or structural features		
Physico-chemical and environmental fate data (note that SI units are preferred for all endpoints)		
Vapour pressure (Pa or mm Hg)		
Water solubility (mg/L)		
Critical micelle concentration		
Octanol/water partition coefficient		
Biodegradation – amount and identity of any stable degradation products		
Hydrolysis as a function of pH		
Other data (please indicate; add additional rows as needed)		
Ecotoxicological information (e.g., LC_{50},[b] NOEC,[c] LOEC,[d] duration, species). Some examples listed below. Add rows as needed.		
Fish chronic toxicity		
Daphnia acute toxicity		
Other data (please indicate; add additional rows as needed)		
Toxicological information (e.g., LD_{50},[e] NOEC, LOEC, duration, species) Some examples are listed below. Add rows as needed.		

Acute mammalian toxicity		
Chronic and sub-chronic toxicity		
Sensitization		
Other data (please indicate; add additional rows as needed)		

[a]CAS registry number – Chemical Abstracts Service Registry Number
[b]LC_{50} – median lethal concentration
[c]NOEC – no-observed-effect concentration
[d]LOEC – lowest-observed-effect-concentration
[e]LD_{50} – median lethal dose

Table 8-6 Comparison Table of the Notified and Surrogate Polymers

Parameter	Notified polymer	Surrogate polymer
CAS registry number[a]		
Chemical name of the polymer		
Representative structural formula (image)		
Monomers with their concentrations		
Monomer 1 name and CAS registry number	(%)	(%)
Monomer 2 name and CAS registry number	(%)	(%)
Monomer 3 name and CAS registry number	(%)	(%)
Polymer molecular weight distribution and polydispersity e.g., M_n[b] / M_w,[c] M_w/M_n		
Weight percent < 1 000 daltons		
Weight percent < 500 daltons		
Reactive functional groups and FGEW[d]		
Other data (please indicate; add additional rows as needed)		

[a]CAS registry number – Chemical Abstracts Service Registry Number

[b]M_n – number average molecular weight
[c]M_w – weight average molecular weight
[d]FGEW – functional group equivalent weight

8.4.4 Quantitative Structure–Activity Relationship Estimates

QSAR estimates provide quantitative estimates of particular properties and are often generated by computer programs that use regression analysis or molecular descriptors that mathematically represent the structural components of a molecule. Linear or multiple regression of a particular property against another property (e.g., octanol/water partition coefficient versus water solubility, or vapour pressure versus boiling point) can be used to derive an empirical relationship for one or several classes of chemicals.

The validity of the QSAR estimate must be explained in the NSN, in terms of whether the estimate is reasonable in comparison with measured data, taking into account the structural features of the notified substance in comparison with the structural features or chemical class used to develop the estimate. The appropriateness of the QSAR must be discussed in terms of the ability of the model to correctly predict the targeted endpoint for the notified substance.

Information to support the acceptance of data based on QSARs should include:

a) a validation of the estimate, including the reporting of types of chemicals and/or structures used to generate the estimate and the experimental data for these chemicals; and
b) the level of confidence associated with the estimate.

A recommended method to support the acceptance of data based on QSARs is presented in the OECD Environment Health and Safety Publications "Series on Testing and Assessment" Document No. 49 *Report from the Expert Group on (Quantitative) Structure–Activity Relationships [(Q)SARs] on the Principles for the Validation of (Q)SARs*[28].

According to the five OECD validation principles, the QSAR model should:

- be associated with a defined endpoint;
- be based on an unambiguous algorithm;
- have a defined domain of applicability;
- be associated with appropriate measures of goodness-of-fit, robustness and predictivity; and
- be associated with a mechanistic interpretation, if possible.

28 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?doclanguage=en&cote=env/jm/mono(2004)24

Any QSAR estimates generated by following these OECD validation principles should be adequately documented using two publicly available reporting formats: the QSAR Model Reporting Format (QMRF) and the QSAR Prediction Reporting Format (QPRF). The QMRF provides validation of the QSAR model itself, while the QPRF provides information about the applicability of the model to the chemical under consideration. Both of these documents should be provided, if available. The NS program will consider the adequacy of any QSAR estimate on a case-by-case basis, taking into account the validity and applicability of the model, as provided in the documentation.

The NS program assesses a wide variety of substances, many of which are considered "model difficult" due to the substance falling outside the applicability domain of a model, with features of the molecule not represented in the training set. Consequently, the NS program advocates the judicious use of modelled data. The use of predictive modelling for estimating substance properties should be limited to classes of well-understood chemicals for which there exists robust models developed with strong training sets.

Although not required, notifiers are encouraged to submit a PNC request (see section 8.8), while the NSN is being prepared, in order to seek advice on the acceptability, use and documentation of estimates obtained from QSAR.

8.4.5 Nanomaterials

Presently, the NS Program considers QSARs on nanomaterials to be under development, and therefore will require evidence that they are sufficiently reliable in using physico-chemical properties to make toxicological predictions. Should a model be submitted to support nanomaterial read-across, a thorough evaluation of its validity and applicability is needed. Notifiers are encouraged to submit a PNC request when submitting surrogate data and/or QSAR estimates to support endpoints for nanomaterials.

8.5 Test Data on UVCBs and Impure Substances

UVCB substances are defined as substances that are of unknown or variable composition, contain complex reaction products or are of biological origin. These materials are derived from natural sources or complex reactions and are considered single substances for notification purposes and under the New Substances provisions of the *Canadian Environmental protection Act,1999* (the Act); therefore, all tests should be performed on the entire UVCB substance. Where a prescribed test is not appropriate (e.g., melting point), the use of alternative methods should be considered (e.g., softening point). Also, the provision of information about any of the known components

of the UVCB substance will assist in the interpretation of data generated on the UVCB substance.

Due to the complex nature of this group of substances, the NS program encourages notifiers to submit any available additional information about starting materials, reaction steps and mechanisms related to the UVCB substances which will assist in the risk assessment.

Difficulties may also occur when testing substances that contain high levels of impurities (e.g., residual starting materials, solvents and by-products), because impurities can confound the interpretation of test data. Consequently, tests should be performed on a high-purity sample of the substance. However, if further purification of the substance is neither technically feasible nor practical, tests on the crude product may be acceptable. In all cases, the purity of the tested material must be stated and information documenting efforts to isolate the substance provided. Information about the physico-chemical or toxicological properties of any of the impurities will assist in the interpretation of the data generated on the impure substance. In cases where information generated about the mixture would not be meaningful for the assessment of the notified substance (e.g., notified substance comprises only a very small proportion of the mixture and further purification is not feasible), a request for a waiver on the grounds of technical infeasibility will be considered.

8.6 Sources of Test Methods

Test methods can be accessed through the OECD, the Environment and Climate Change Canada or the United States Environmental Protection Agency (US EPA) websites.

8.6.1 Organisation for Economic Co-operation and Development

OECD TGs and GLP are available at

https://www.oecd.org/chemicalsafety/testing/

a) *OECD Guidelines for Testing of Chemicals* (November 2004)
b) "Principles of Good Laboratory Practice" (July 2001)

8.6.2 Environment and Climate Change Canada Biological Test Methods

Environment and Climate Change Canada biological test methods are available at

https://www.canada.ca/en/environment-climate-change/services/wildlife-research-landscape-science/biological-test-method-publications.html

a) Environment Canada. *Biological Test Method: Acute Lethality Test Using Rainbow Trout* (July 1990, amended May 1996, May 2007). Report EPS1/RM/9.
b) Environment Canada. *Biological Test Method: Acute Lethality Test Using Daphnia spp.* (July 1990, amended May 1996). Report EPS1/RM/11.

c) Environment Canada. *Biological Test Method: Growth Inhibition Test Using a Freshwater Algae* (second edition: March 2007). Report EPS1/RM/25.
d) Environment Canada. *Biological Test Method: Reference Method for Determining Acute Lethality of Effluents to Rainbow Trout* (second edition: December 2000, amended May 2007, February 2016). Report EPS1/RM/13.

8.6.3 United States Environmental Protection Agency

US EPA test methods are available at

https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=91014VJA.txt

a) *Algae Acute Toxicity Test U.S. Environmental Protection Agency Environmental Effects Testing Guidelines* (August 1982). EPA 560/6-82-002, PB 82-232992.

8.7 Waiver Requests for Information Requirements

8.7.1 Introduction

Under subsection 81(8) of the Act, a request to waive the requirement for any of the prescribed information may be made to the NS program. The decision to grant a waiver will be made on a case-by-case basis and will depend on whether at least one of three criteria has been met. The statutory criteria for a waiver of information, identified in subsection 81(8) of the Act, are the following:

(*a*) in the opinion of the Ministers,[29] the information is not needed in order to determine whether the substance is toxic or capable of becoming toxic;

(*b*) the substance is to be used for a prescribed purpose or manufactured at a location where, in the opinion of the Ministers, the notifier requesting the waiver is able to contain the substance so as to satisfactorily protect the environment and human health; or

(*c*) it is not, in the opinion of the Ministers, practicable or feasible to obtain the test data necessary to generate the information.

Waiver requests may be submitted in writing as part of the NSN and should include a well-documented scientific rationale to support each request as well as an identification of the statutory criterion under which the request is being made. Failure to provide a proper rationale with supporting documentation will result in a delay of the start of the

[29] Refers to both the Minister of the Environment and Minister of Health

assessment period (see sections 9.3.3 and 9.3.4). To determine whether waivers are acceptable and to avoid unnecessary delays, the NS program provides the opportunity for and encourages notifiers to submit a PNC request (see section 8.8) while the NSN is being prepared.

Appendix 6 of this Guidance Document provides examples of conditions under which waivers may be granted. This list is not intended to be exhaustive, but describes some independent conditions that, in most cases, would be considered to be sufficient justification to grant a waiver. Waiver requests may also be based on a combination of factors (e.g., physical properties, inherent toxicity and potential for exposure to the substance).

Once the waiver is granted, its particulars will be published in the *Canada Gazette*, Part I, in accordance with subsection 81(9) of the Act. The published waiver notice will contain only a) the name of the notifier (or company) to whom the waiver is granted; and b) the type of information to which it relates (e.g., Company X, Data from a ready biodegradability test). The notice will not specify the substance to which the waiver applies or the NSN reference number.

Generally, the eligibility of a substance for addition to the DSL will not be affected by waivers granted under paragraphs 81(8)(*a*), 81(8)(*b*) or 81(8)(*c*) of the Act.

When waivers have been granted, the notifier must provide any corrections to the information used to justify and assess the waivers as per subsection 81(11) of the Act (see section 10.1.1). The Minister of the Environment may then, if necessary, request that the notifier provide the information item that was waived or take appropriate control measures.

A waiver should not be requested when information to address the data element is provided about a surrogate substance or using alternative methods.

8.7.1.1 Waivers Requested under Paragraph 81(8)(a) of the Act

A waiver may be granted if it can be established that the test is unnecessary to determine whether the substance is toxic or capable of becoming toxic. In cases where the requirement for one part of a prescribed test depends on the result of a previous part (e.g., mutagenicity test data), it is suggested that the tests be completed based on a self-evaluation of test results or a consultation with the NS program through a PNC request (see section 8.8). After receipt of the PNC request or the NSN, the NS program will assess the submitted information to determine whether the information provided is acceptable.

8.7.1.2 Waivers Requested under Paragraph 81(8)(b) of the Act

A waiver may be granted if the substance is to be used for a purpose prescribed by regulations. No regulations have been developed in relation to these waivers.

Waivers may also be granted if the substance is manufactured at a location where, in the opinion of the Ministers, the person requesting the waiver is able to contain the substance so as to satisfactorily protect the environment and human health.

8.7.1.3 Waivers Requested under Paragraph 81(8)(c) of the Act

Many of the potential waivers that can be requested under paragraph 81(8)(*c*) relate to instances where it is technically arduous or impossible to perform the required tests using conventional technology because of the physical or chemical properties of the substance.

The use of alternative protocols or surrogate data to fulfill the information requirement should be considered before it is judged to be infeasible or impractical to provide certain information. In these cases, a waiver should not be requested. The cost of obtaining data cannot be used as the sole reason for the infeasibility or impracticability of providing the prescribed information.

8.7.2 Class Considerations of Waivers

As a result of the NS program's experience in assessing new substances, a body of knowledge now exists on classes of substances that can be applied to newly notified substances in those classes. A systematic review of the properties of a class, corresponding to regulatory requirements, can reveal established trends in its properties. In such cases, information for specified endpoints for notified members of the class will likely not be needed to determine whether the substance is toxic or capable of becoming toxic.

Notifiers who are preparing NSNs for substances that meet the definition of such a class may request waivers in relation to data concerning specified endpoints under paragraph 81(8)(*a*) of the Act.

Notifiers may contact the NS program through the Substances Management Information Line to discuss the information needed to prepare a nomination.

The NS program website will be updated as definitions of classes are developed. The NS program website at https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html should be checked for any new information about available classes.

8.7.2.1 Cationic Class Waivers

Available information is considered sufficient to indicate that a class comprising certain cationic polymers is expected to have low toxicity in the health toxicological tests

prescribed in the Regulations. Thus, notifiers may request waivers for all the toxicological test requirements for polymers that meet this class definition.

Currently, this class is defined as polymers that are Non-reduced Regulatory Requirement polymers solely due to the presence of the following cationic or potentially cationic groups:

- primary, secondary or tertiary amine groups;
- carbodiimides; or
- sulphoniums.

Polymers containing other cationic polymers (such as quaternary amines, hindered amines, azides, isocyanates (free and blocked) and phosphoniums) are not included in the above class definition, either because there is currently insufficient information available regarding their toxicity to warrant their inclusion or because available information indicates that there are adverse effects associated with them. For cationic polymers that do not meet the above definition and therefore are not eligible for a class waiver, notifiers may still request waivers with sufficient rationale for specific tests or submit surrogate information for consideration by the NS program on a case-by-case basis. As well, polymers with a M_n greater than 10 000 daltons will generally not be eligible for waivers for acute and repeated-dose toxicity tests if inhalation is expected to be the most significant route of exposure for the general population based on expected use.

8.8 Pre-Notification Consultation

A PNC is an option for notifiers who wish to consult with the NS program during the planning or preparation of their NSN to discuss any questions or concerns they have about the required prescribed information. The notifier may submit his or her request for a PNC through the Substances Management Information Line. Although not required, a PNC request is recommended when clarification is needed on the notification procedures or information requirements and assistance is needed in determining the acceptability of

a) waiver requests;
b) test protocols;
c) consolidated notifications
d) data based on calculation or estimation methods (e.g., structure–activity relationships); or
e) other endpoints (see section 6.5.4).

PNC requests can be addressed in writing (by mail or e-mail) or through a meeting or conference call.

For meeting and conference call PNC requests, the NS program will make every effort to respond to the proposed queries during the meeting. The NS program requests a

minimum of two weeks between receiving the preliminary PNC request, which contains sufficient information, and conducting the meeting. This allows time for the NS program to make an informed response to the question(s) at hand during the meeting.

For chemicals and polymers PNC requests, the NS program will make every effort to respond in writing to the queries within a period of 30 days. This period will start after sufficient information has been provided for the PNC request to proceed.

The information required to begin a PNC includes

- Substance information (substance name, CAS registry number, structure, reactants);
- Contact information (contact name, title, company, email, and mailing address);
- Intended notification Schedule of the Regulations;
- Intended use of the substance;
- The specific questions and/or concerns to be answered by the NS program;
- Any data and test reports in the notifier's possession, if applicable;
- Confidential Business Information (CBI) claims (corporation, manufacture, import, amount, substance identity, use, or in commerce), if applicable; and
- A brief agenda, if a conference call is requested.

The NS program will give opinions based on the information received with the PNC request. The professional opinions of the NS program, expressed during the PNC, are not an official commitment, since technical conclusions may differ after a more in-depth assessment has been conducted on the complete NSN.

In addition to PNC requests, the NS program encourages discussions to clarify any other issues related to the NS program.

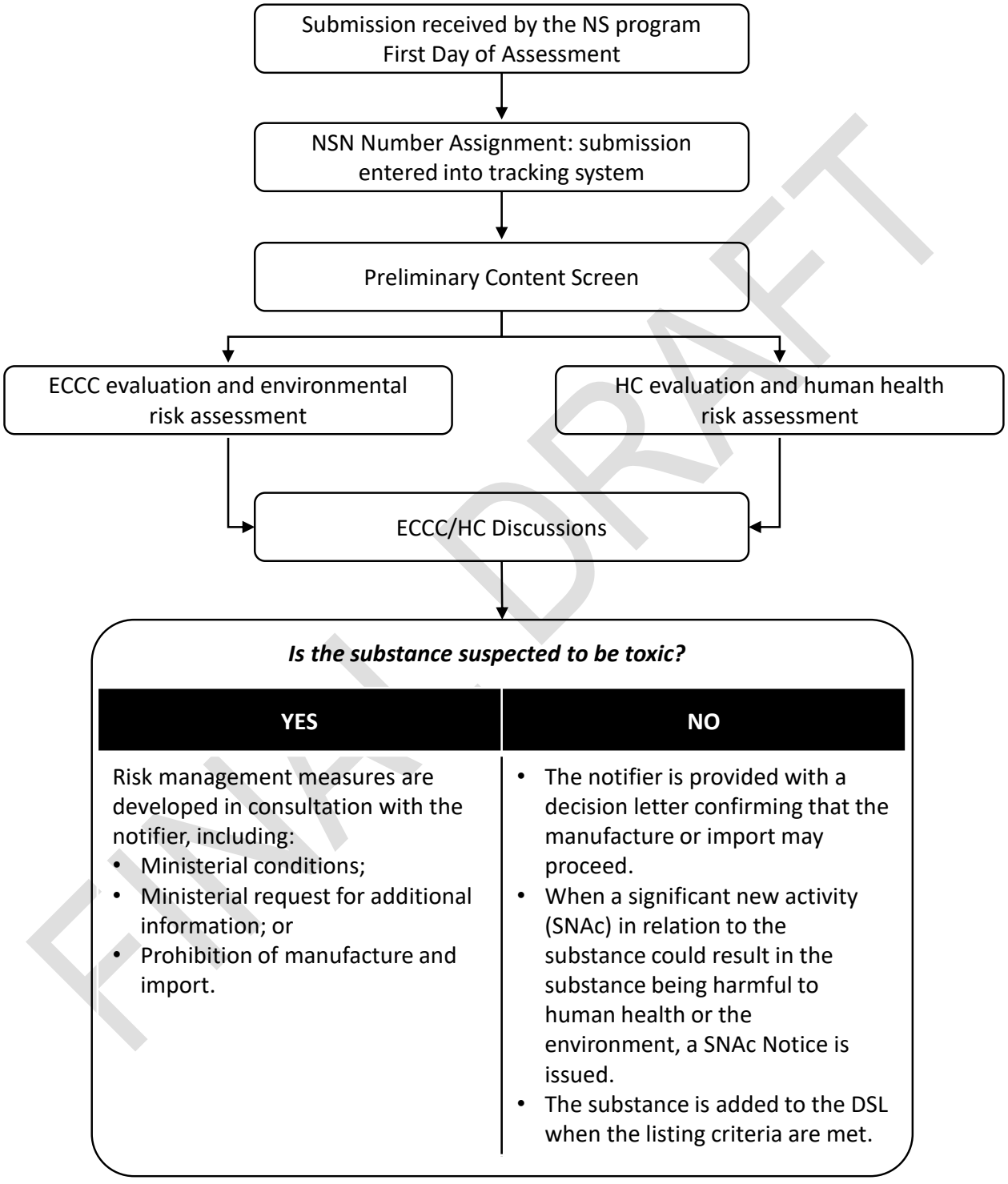
SECTION 9 — PROCESSING A NEW SUBSTANCES NOTIFICATION

This section describes the administrative procedures and responsibilities of the New Substances (NS) program when a New Substances Notification (NSN) is received.

9.1 Overview of the New Substances Notification Assessment Process

Figure 9-1 gives an overview of the assessment process from the day the NSN is received by the NS program to the day the substance is added to the Domestic Substances List (DSL) or risk management measures are taken on the substance.

Figure 9-1 Overview of the New Substances Notification Assessment Process



ECCC = Environment and Climate Change Canada HC = Health Canada

9.2 Receipt of a New Substances Notification

9.2.1 Assessment Period

The assessment period refers to time, in calendar days, allotted for the NS program to assess a NSN. The number of days for an assessment period is indicated in Table 1-1.

Day 1 of an assessment period is the day following the day on which the complete NSN is received by the NS program. The assessment period may be affected by missing or incomplete information. For example,

a) if an NSN is submitted without fees or with an unacceptable method of payment for the fees (see fee table on the NSN fees webpage[30], the assessment period will not begin until the fees are received;
b) if an NSN is grossly inadequate or missing information prescribed in the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations), the assessment period will not begin until a corrected NSN has been received;
c) if proprietary information is being sent directly to the NS program by a Third Party Information Supplier, the assessment period will not start until all the required information has been received;
d) if minor information is found to be missing or erroneous, the assessment period will would continue, provided the correct information is supplied by a date specified by the program (usually within a couple of working days); or
e) if, during the assessment period, the information within the NSN is found to be incomplete or erroneous, it will be deemed incomplete and the assessment period will be restarted on Day 1 once the complete NSN has been submitted.

9.3 Correspondence

Official correspondence between the NS program and the notifier or the “Canadian Agent” will occur throughout the assessment process. The NS program will communicate with the notifier via e-mail. Notifiers who still wish to receive correspondence by mail should make the request in their NSN cover letter. If no such request is made, originals will not be sent by mail. Sections 9.3.1 to 9.3.7 describe types of correspondence a notifier may receive for NSNs and Significant New Activity Notifications (SNANs).

9.3.1 Notice of Initiation

When a Third Party Information Supplier (see section 5.2) is involved in an NSN, the notifier must submit a partial NSN to initiate the process. A notice of initiation is issued to the notifier to acknowledge receipt of this partial information that is required to

[30] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

complete the NSN. The assessment period does not start until all of the prescribed information has been provided by the Third Party Information Supplier. Once the complete package of information has been received, a notice of acknowledgement of the complete NSN is issued (see section 9.3.2), and the assessment period will start.

9.3.2 Notice of Acknowledgement of Complete New Substances Notification

After receipt and acceptance of the information provided in the NSN, a notice of acknowledgement will be issued specifying the starting date of the assessment period and the NSN reference number. A notice of acknowledgement indicates that the administrative information is satisfactory and that all prescribed information including the prescribed fees have been received, but the file has not yet been assessed. The notice of acknowledgement also provides the expected end date of the assessment period.

A notifier may, either at the time of filing or after an NSN has been filed, request an early termination of the assessment period (subsection 83(6) of the *Canadian Environmental Protection Act, 1999* (the Act)) specified for that specific Schedule in the the Regulations. A notifier may include a target date for early termination and a reason for why early termination is being requested. If such a request is received, the notice of acknowledgement would indicate that the NS program will consider the request during the assessment period. A request for early termination does not guarantee accommodation.

9.3.3 Notice of Missing Information

A notice of missing information will be issued if the NSN contains omissions or errors in the mandatory prescribed information requirements. This notice will describe all deficiencies in the NSN. See section 9.2.1 of this Guidance Document for examples of reasons for this type of notice. The assessment period does not start until all the required information has been received and accepted. If the omissions or errors are identified following the communication of a notice of acknowledgement of complete NSN, the assessment period may be restarted at Day 1 when the additional or corrected information is received.

9.3.4 Notice of Rejection

A notice of rejection will be issued if the NSN contains significant omissions or errors in the mandatory information requirements. This notice will describe all deficiencies in the NSN. Original documentation may be returned. See section 9.2.1 of this Guidance Document for examples of reasons for this type of notice.

9.3.5 Notice of Extension of Assessment Period

All NSNs and SNANs are eligible to have their assessment periods extended when additional time is required to complete an assessment. The notifier will be issued a notice of extension of assessment period extension at or before the end of the initial assessment period, advising them that the assessment period has been extended. The Minister of the Environment (the Minister) may extend the assessment period only once, for a length of time not exceeding the time prescribed for the initial assessment period.

9.3.6 Notice of Conclusion of Assessment Period

The conclusion of the assessment will be communicated to the notifier at or before the end of the applicable assessment period.

Note: Pursuant to subsection 83(6) of the Act, the assessment period of an NSN or SNAN may be terminated early. These provisions would be implemented when the evaluation is completed prior to the end of the prescribed assessment period. In such a case, the notice would indicate the day on which the assessment period ends.

Based on the assessment conclusions (see section 9.6), the notice will indicate that

- there is no suspicion that the substance is toxic or capable of becoming toxic;
- there is no suspicion of toxicity for the current activities associated with the substance, but it is suspected that other activities could result in the substance becoming toxic; or
- there is a suspicion of toxicity and risk management measures are imposed.

When applicable, the notice will also indicate that manufacture or import may begin either in amounts exceeding the quantity that triggered the notification, or in accordance with the terms of the risk management measures imposed.

The notice may also include any additional information required for the substance to become eligible for addition to the DSL.

9.4 Withdrawing a New Substances Notification

A notifier may request that an NSN be withdrawn if it is determined that

a) the substance has been previously notified by the same company at that threshold;
b) the substance is already listed on the DSL; or
c) the notifier no longer intends to manufacture or import the substance in a quantity at or above the threshold, and the quantity already manufactured or imported does not exceed this threshold.

Withdrawal requests for NSNs can be e-mailed or mailed to the NS program. Withdrawal requests will not be accepted if the notifier has been informed of a proposed decision to take risk management measures or issue a Significant New Activity (SNAc) Notice for the substance. The notifier will be advised in writing as to whether the withdrawal request has been accepted or rejected.

9.5 Assessment of the New Substances Notification

The purpose of the assessment and risk management process is to ensure that, either because of the inherent properties of the substance or because of measures taken to

mitigate exposure to the substance, the use of the substance will not pose a risk to human health or the environment.

9.5.1 Information Review

Evaluators within the NS program will assess the NSN to determine the acceptability of

- the substance identity and masked names;
- claims for Confidential Business Information;
- test protocols and procedures;
- test data;
- rationales for requests for waivers of information;
- rationales for use of alternative test protocols or surrogate information; and
- exposure information.

Deficiencies in the submitted information that cannot be easily resolved may result in rejection of the NSN and termination of the assessment period (see section 9.3.4).

9.5.2 Determination of Toxicity

The purpose of the NSN assessment process is to determine whether or not the substance is toxic or capable of becoming toxic as per any of the criteria set out in section 64 of the Act and stated below:

> **64.** […] a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that
>
> (*a*) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
>
> (*b*) constitute or may constitute a danger to the environment on which life depends; or
>
> (*c*) constitute or may constitute a danger in Canada to human life or health.

Consequently, the determination of whether a substance is, or is suspected of being, toxic or capable of becoming toxic involves assessment of the potential for exposure of humans and components of the environment and of the adverse effects of the substance on humans or the environment (including other living organisms, interacting natural systems and the abiotic components of the environment).

The potential for exposure to a substance depends on the quantity, rate, frequency and conditions of release of the substance into the environment at all points in its life cycle, as well as the mobility, environmental compartmentalization and persistence of the substance. The exposure assessment considers the use of the substance identified by

the notifier, as well as other possible ways in which the substance might be used if it were listed on the DSL without restrictions.

The assessment of adverse effects on humans and other living organisms considers endpoints such as lethality, mutagenicity, reproductive and developmental effects and organ toxicity, whereas adverse effects on the abiotic components of the environment include consequences such as depletion of the ozone layer, global warming and production of acid rain.

A substance may be suspected of being toxic if either the adverse effects of a substance or the potential exposure to a substance is of concern. For example, substances with considerable potential for exposure because of continuous release of high quantities or persistence in the environment may be suspected of being toxic, although there may be uncertainty regarding any biological or environmental hazard from the information available for the initial assessment. When an assessment has led to a “suspicion of toxicity,” the Act has a unique provision, under subsection 84(1), which permits the Minister to undertake one of several risk management measures (see section 9.6).

9.6 Assessment Conclusions

There are three possible outcomes of an assessment:

a) There is no suspicion of toxicity, and no action is taken.
b) There is no suspicion of toxicity for the current activities associated with the substance, and a SNAc Notice is published for the substance because it is suspected that other activities could result in the substance becoming toxic (see section 9.6.2).
c) There is a suspicion of toxicity, and risk management measures are imposed (see section 9.6.3).

The notifier will be advised in writing, before the end of the assessment period, if the NS program suspects that the substance is toxic or capable of becoming toxic, and will be informed as to what action will be taken. The notifier will also be advised in writing, before the end of the assessment period, if the NS program intends to develop a SNAc Notice in relation to the substance (see section 9.6.2).

9.6.1 No Suspicion of Toxicity and No Action Taken

If the completed environmental and human health assessment reports on the notified substance determine that there is no suspicion that the substance is toxic or capable of becoming toxic, no action is taken. If no action is taken prior to the end of the assessment period, the notifier may, after the assessment period has expired, commence manufacturing or importing the substance in amounts exceeding the quantity that triggered the notification.

9.6.2 Significant New Activity Notices

A new substance assessment takes into consideration potential risks concerning the notified activities as well as any other possible activities involving the substance. When there is suspicion that a significant new activity may result in the substance becoming toxic, the SNAc provisions of the Act (see section 85 of the Act) can be applied to a new substance with the publication of a SNAc Notice in the *Canada Gazette*, Part I. A SNAc Notice is published within 90 days of the end of the assessment period. Typically, the notifier is informed of the development of a SNAc Notice prior to the end of the assessment period.

A SNAc Notice describes activities that may result in:

- a significantly greater quantity or concentration of the substance in the environment; or
- a significantly different manner or circumstances of exposure to the substance.

The SNAc Notice includes:

- the identification of the substance (by explicit substance name, or by masked name if claimed confidential);
- a description of the significant new activities;
- a description of the information that must be provided to the Minister before the start of the significant new activity;
- timelines for the notifier to provide the information; and
- the period for the Minister of the Environment and the Minister of Health (the Ministers) to assess the information.

A SNAc Notice applies to anyone using the substance. Any person wishing to engage in a significant new activity in relation to the substance is required to submit a SNAN to the Minister containing all of the information prescribed in the Notice prior to using the substance for the proposed activity. After the complete information is received, the Ministers will conduct risk assessments of the substance in relation to the proposed significant new activity within the timelines set out in the Notice.

Reporting obligations under the Regulations and the Act apply, whether or not a SNAc Notice has been issued for a new substance. Where applicable, the notifier is required to provide:

- the subsequent Schedules of information under the Regulations, if necessary;
- the prescribed additional information in subsection 7(2), 7(3), 11(2) or 11(3) of the Regulations in the case of high release or significant public exposure; and
- the appropriate notice to fulfill the DSL listing criteria (see section 10).

The substance may become eligible for addition to the DSL once the above-mentioned information has been received, accepted and assessed. Until the substance is added to

the DSL, other notifiers must continue to notify the manufacture or import of the new substance as specified by the Regulations.

The SNAc provisions of the Act can also be applied to a substance on the DSL with the publication of a SNAc Order in the *Canada Gazette,* Part II. When a substance subject to a SNAc Notice is added to the DSL, this SNAc Notice no longer applies. To maintain the reporting obligations on the substance, the SNAc requirements are added to the DSL with the publication of a SNAc Order.

After a complete SNAN is received, the NS program will assess the information within the time period specified by the SNAc Notice or SNAc Order. From the assessment of this information, SNAc requirements may be varied or rescinded, or other risk management measures may be imposed, if necessary (see section 9.6.3).

9.6.3 Risk Management Measures

When a substance is suspected to be toxic or capable of becoming toxic, risk management measures may be applied to mitigate any risk to human health or the environment. Notifiers will be advised, prior to the end of the assessment period, that there are concerns with the substance. Usually the assessment period is extended (see section 9.3.5), which provides time to develop the risk management measure and obtain Ministerial approval. The notifier will be advised of the extension of the assessment period and of proposed risk management measures prior to the end of the initial assessment period.

Section 84 of the Act states that when the Ministers suspect that a substance is toxic or capable of becoming toxic, the Minister may

a) permit any person to manufacture or import the substance subject to specified conditions;
b) prohibit any person from manufacturing or importing the substance for a period not exceeding two years (this prohibition lapses at the end of the two-year period unless, before the end of this period, a notice of proposed regulations under section 93 of the Act is published in the *Canada Gazette*); or
c) prohibit the manufacture or import of the substance until additional information or test results have been submitted to the Minister (subsection 84(2) of the Act) and assessed (the assessment period for this supplementary information expires 90 days after receipt of the information).

These measures must be taken by the Minister before the expiration of the assessment period. A copy of the Ministerial correspondence and notice will be e-mailed to the notifier. When a condition or prohibition is issued or varied, the notice must be published in the *Canada Gazette* describing the action and the substance to which it applies. A substance that is subject to conditions imposed pursuant to section 84(1)(a) of the Act cannot be added to the DSL.

9.6.3.1 Conditions under Paragraph 84(1)(a) of the Act

When a substance is suspected to be toxic or capable of becoming toxic, conditions may be imposed to mitigate any risk to human health or the environment. Conditions under paragraph 84(1)(*a*) of the Act allow the manufacture or importation of a substance with restrictions. Types of restrictions on the substance include, but are not limited to

- the quantity allowed;
- the physical form (e.g., must be imported as a plastic pellet);
- the use; or
- the disposal of the substance or containers that held the substance.

The notifier and, if prescribed, the notifier's customers are obliged to abide by the conditions imposed on the substance by the Minister and keep records as indicated. Ministerial conditions are published in the *Canada Gazette*, Part I, after they have been issued to the notifier. Substances subject to Ministerial conditions are not eligible for addition to the DSL. Therefore, any new notifier who wishes to manufacture or import the same substance must submit an NSN, as prescribed by the Regulations. This may result in the same or similar conditions being imposed.

A notifier may submit additional information and request a re-evaluation of the decision made by the NS program. The NS program will review and consider this additional information and may amend or rescind the conditions. The conditions stand unless a notice is published in the *Canada Gazette* to amend or rescind the conditions based on the additional information.

9.6.3.2 Prohibitions under Paragraph 84(1)(b) of the Act

When a substance is suspected to be toxic or capable of becoming toxic, a prohibition may be imposed to mitigate any risk to human health or the environment. Prohibitions imposed under paragraph 84(1)(*b*) of the Act prohibit any person from manufacturing or importing the substance in any amounts. Ministerial prohibitions are published in the *Canada Gazette*, Part I, after they have been issued to the notifier. Subsection 84(4) of the Act states that this prohibition expires two years after it is imposed unless, before the expiry of the two years, the Governor in Council publishes in the *Canada Gazette* a notice of proposed regulations under section 93 of the Act in respect of the substance, in which case the prohibition expires on the day the regulations come into force.

The notifier may submit additional information and request a re-evaluation of the decision made by the NS program. The NS program will review and consider this additional information and may amend or rescind the prohibition or take alternative risk management measures. The prohibition stands unless a notice is published in the *Canada Gazette* to amend or rescind the prohibition.

9.6.3.3 Request for Additional Information under Paragraph 84(1)(c) of the Act

When the NS program requires additional information to be provided to determine whether the substance is toxic or capable of becoming toxic, a request for additional information with a prohibition of manufacture or import pending this testing may be imposed to mitigate any risk to human health or the environment. The request for additional information is imposed under paragraph 84(1)(*c*) of the Act, and the prohibition of manufacture or import is imposed under subsection 84(2) of the Act. Subsection 84(2) of the Act states that the person who is required to submit the information is prohibited from manufacturing or importing the substance unless the information is provided and a period of 90 days after the additional information was provided has expired. Once the required additional information has been submitted it will be assessed to determine whether the substance is toxic or capable of becoming toxic and whether further risk management measures are required.

SECTION 10 – POST-NOTIFICATION RESPONSIBILITIES

10.1 Notifier's Responsibilities

The onus is on the notifier to ensure that all information provided to the New Substances (NS) program is accurate and complete.

10.1.1 Correction of Information

Under subsection 81(11) of the *Canadian Environmental Protection Act, 1999* (the Act), any notifier who has submitted information in support of a New Substances Notification (NSN) and later finds that the information is erroneous must immediately notify the NS program, via correspondence, of that fact and submit the necessary correction to their NSN.

This requirement relates only to the correction of information that existed at the time the NSN was submitted.

10.1.2 Section 70 of the Act

Information generated after a NSN was submitted which reasonably supports the conclusion that the substance is toxic or is capable of becoming toxic must be provided to the NS program under the provisions of section 70 of the Act. This information must be provided unless the notifier has actual knowledge that the NS program already has the information.

To obtain the procedures for submitting information under section 70 of the Act, contact the Substances Management Information Line.

10.1.3 Notice of Excess Quantity

Under subsection 81(14) of the Act, a notifier who has met the requirements to manufacture or import a substance, other than research and development, contained site-limited intermediate or contained export-only substances, is required to submit a Notice of Excess Quantity (NOEQ) within 30 days of exceeding manufacture or import trigger quantities (see section 10.1.3.1). The information required in a NOEQ is indicated in section 10.1.5 of this Guidance Document.

10.1.3.1 Trigger Quantities

As prescribed in sections 17 and 18 of the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) and subsection 81(14) of the Act, any notifier who did not provide a Notice of Manufacture or Import (NOMI) (see section 10.1.4) must provide a NOEQ within 30 days of meeting one of the following trigger quantities:

a) in the case of a chemical or a biochemical not on the Non-domestic Substances List (NDSL), a quantity that exceeds 10 000 kg in any calendar year; or

b) in the case of a chemical or a biochemical that is listed on the NDSL, a quantity that exceeds in any calendar year:
   i) 50 000 kg if:
      A) the chemical or biochemical is released to the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment, or
      B) the public may be significantly exposed to the chemical or biochemical in a product, or
   ii) 10 000 kg, in any other case.
c) in the case of a Reduced Regulatory Requirement (RRR) polymer, a quantity that exceeds 1 000 kg in any calendar year; and
d) in the case of any other polymer or biopolymer, a quantity that exceeds in any calendar year:
   i) 50 000 kg if the polymer or biopolymer is listed on the NDSL or the polymer or biopolymer is not on the NDSL but all of its reactants are listed on the Domestic Substance Lists (DSL) or the NDSL and:
      A) that polymer or biopolymer is released to the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment, or
      B) the public may be significantly exposed to that polymer or biopolymer in a product, or
   ii) 10 000 kg, in any other case.

10.1.4 Notice of Manufacture or Import

Alternatively, paragraphs 17(2)(*a*) and 18(2)(*a*) of the Regulations prescribe the requirement for a NOMI for chemicals and polymers. This type of notice is an alternative to the requirement for the submission of a NOEQ so that a substance may be eligible for listing on the DSL under paragraph 87(5)(*a*) of the Act without requiring the tracking of manufacture or import quantities. The information required in a NOMI is indicated below.

10.1.5 Content and Submission of the Notices

Any notifier who has submitted the full complement of information for a substance and has begun to manufacture or import the substance may submit a NOMI at any time prior to reaching the trigger quantities specified in section 17 or 18 of the Regulations (see section 10.1.3.1). A notifier who has previously notified a substance for which the full complement of information was not provided and who has begun to manufacture or import the substance in limited quantities may submit the NOMI at the same time as submitting the full complement of information for that substance.

Any notifier who has submitted the full complement of information for a substance and chooses not to submit a NOMI is required to submit a NOEQ within 30 days of meeting the trigger quantities, as indicated in section 10.1.3.1 above.

The NOEQ or NOMI must be signed by the representative of the resident manufacturing or importing the substance as the “Notifier” or the agent of the non-

resident importer of the substance as the “Canadian Agent.” The notice should state the following:

- the person’s name and company name;
- the name of the substance and its approved masked name (if applicable);
- the NSN reference number of the NSN for which the full complement of information was submitted for that substance; and
- a statement indicating the trigger quantity (see section 10.1.3.1) that was exceeded (this information is required only for a NOEQ); or
- a statement indicating that the substance has been manufactured or imported (this information is required only for a NOMI; see section 10.1.4).

The above information must be submitted to one of the addresses in the Comments and Inquiries section of this Guidance Document.

Once either notice is received by the NS program, the substance may be eligible for listing on the DSL if all other requirements described in section 87 of the Act have been met (see section 10.2.1).

10.2 The New Substances Program’s Responsibilities

10.2.1 Additions to the Domestic Substances List

Pursuant to section 87 of the Act, a substance must be added to the DSL and, if listed on the NDSL, deleted from that list within 120 days after the following conditions are met:

a) the information prescribed in section 81 or 82 of the Act and any additional information or test results required under subsection 84(1) of the Act have been provided;
b) the period for assessing the information under section 83 of the Act has expired;
c) no conditions have been imposed on the substance under paragraph 84(1)(a) of the Act;
d) justification has been provided to warrant confidentiality requests, if applicable (see section 2.1.2); and
e) a NOMI has been received which satisfies that the substance has been manufactured or imported as specified in section 10.1.4; or
f) a NOEQ has been received within 30 days of exceeding manufacture or import trigger quantities as specified in section 10.1.3.1.

Substances that are not anticipated to pose a risk to the environment and human health, regardless of their current use, quantity or any other anticipated activity, will be listed on the DSL without restrictions. Substances that may have a significant new activity that may change the outcome of the assessment will be added to the DSL with a flag requiring additional notification requirements (see sections 2.1.4 and 9.6.2). Polymers that are not anticipated to pose a risk to the environment and human health

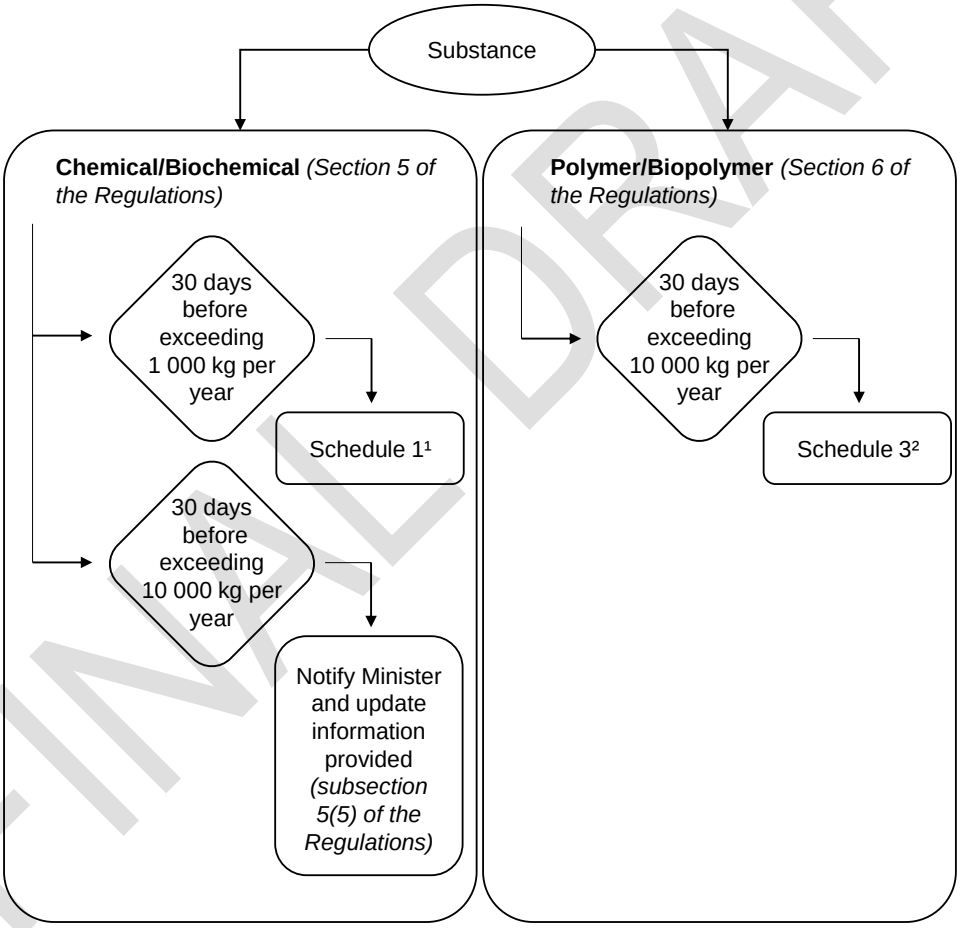
and life when manufactured or imported as an RRR polymer will be added to the DSL with a flag requiring renotification if they are subsequently manufactured in or imported into Canada in a form that no longer meets the RRR criteria.

When the identity of a DSL-eligible substance is claimed confidential by the notifier and an acceptable masked name has been provided, a Confidential Substance Identity Number is assigned to that substance and is provided to the notifier. This Confidential Substance Identity Number and acceptable masked name are then published on the DSL.

Appendix 1 - Flowcharts

The decision schemes shown in this appendix can be used to determine the required Schedule of information for a substance under the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations). The information requirements for each subdivision are cumulative. When consulting the flowcharts, the user should first choose the appropriate flowchart according to the type of substance they wish to notify. The flowcharts will guide the user in identifying what information is to be provided and when it is to be provided, based upon the quantity that triggers the requirement to provide the information.

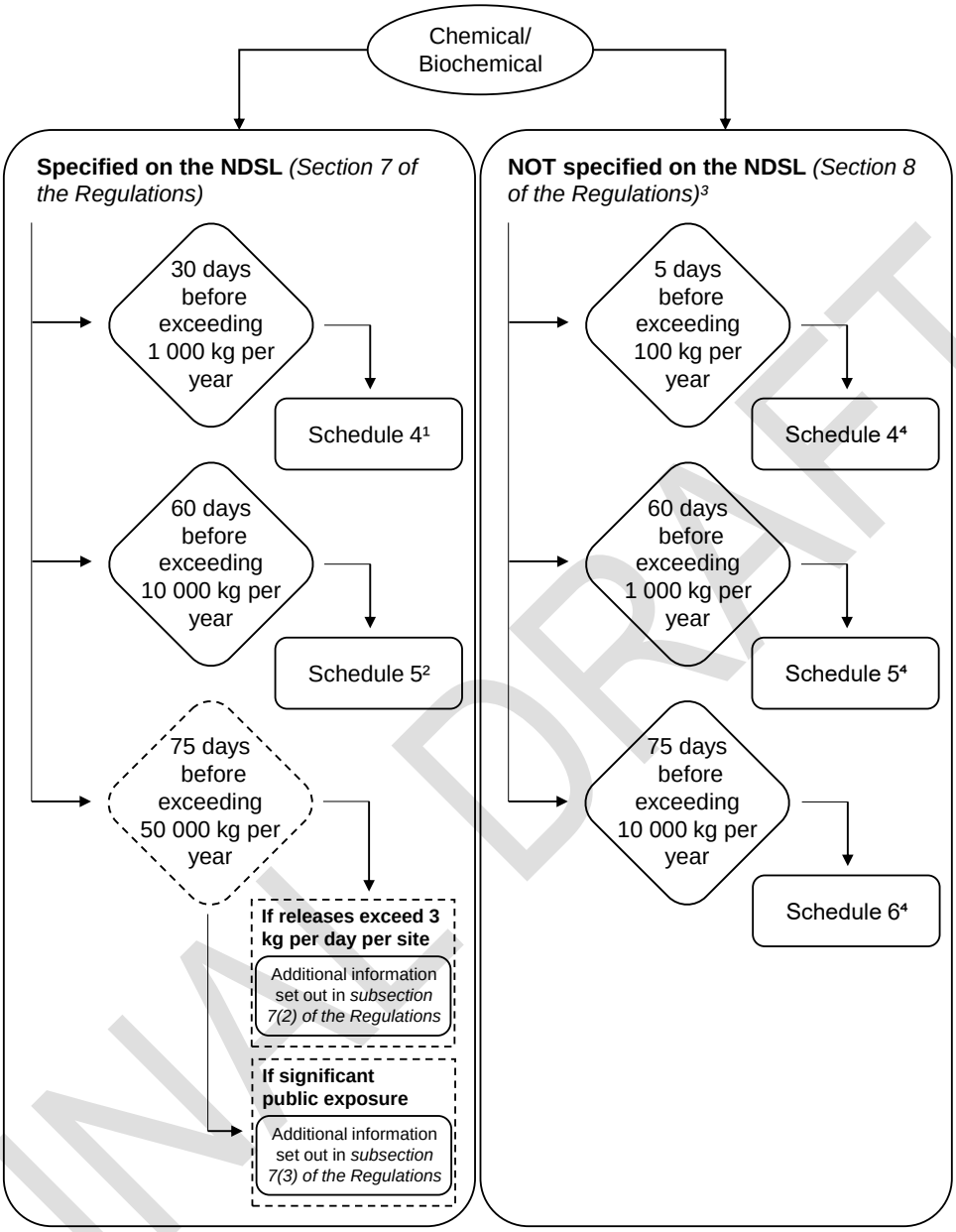
Figure A1-1 Research and Development, Contained Site-Limited Intermediate or Contained Export-Only Substances



[1] Additional information specified in Schedule 2 is also required if the chemical is a biochemical *(see subsections 5(2), (3) and (4) of the Regulations)*.

[2] Additional information specified in Schedule 2 is also required if the polymer is a biopolymer *(see subsections 6(2), (3) and (4) of the Regulations)*.

Figure A1-2 Chemical / Biochemicals Other Than Those In Figure A1-1



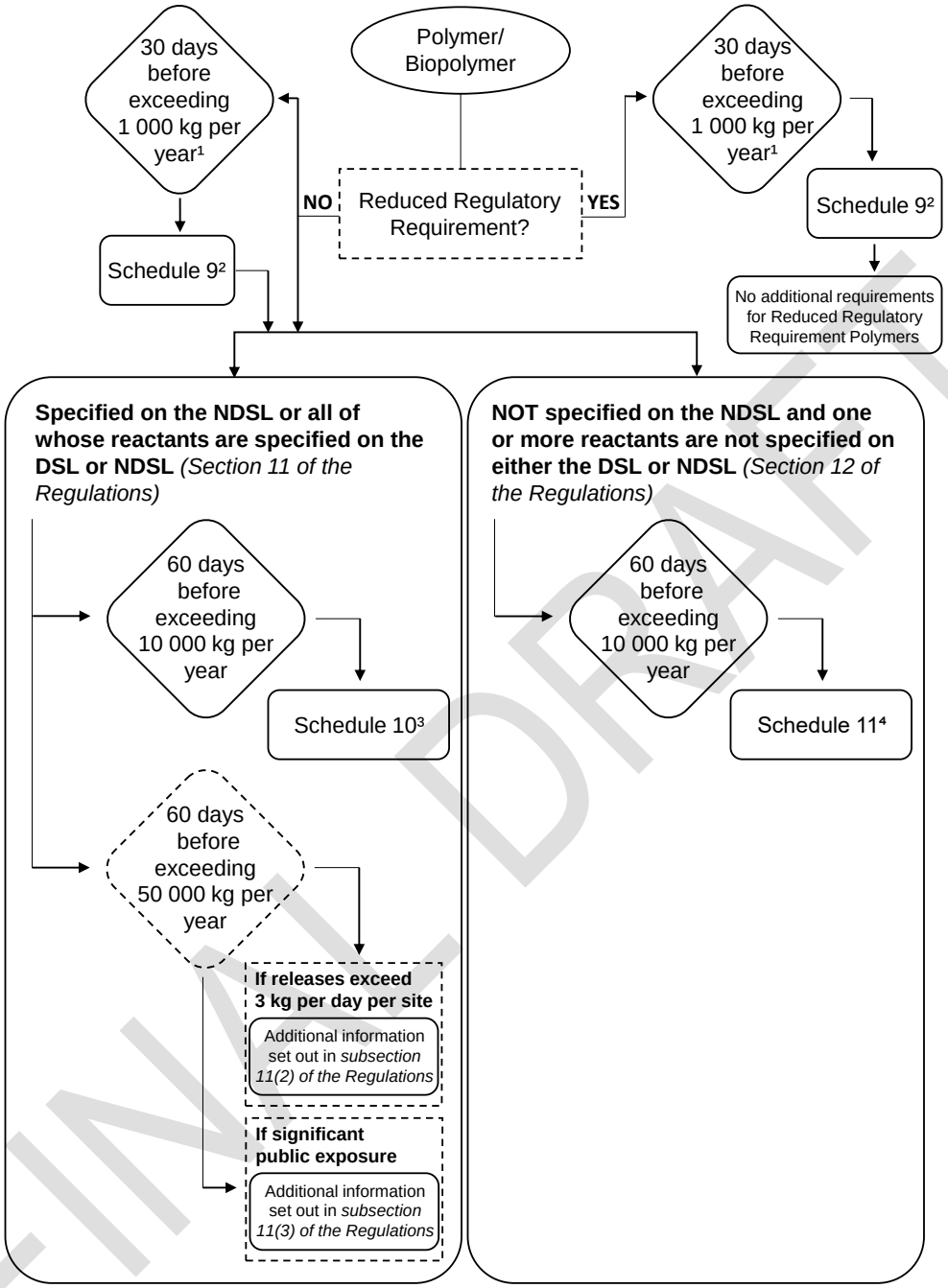
[1] Additional information specified in Schedule 2 is also required if the chemical is a biochemical *(see subparagraph 7(1)(a)(ii) of the Regulations)*.

[2] Additional information specified in Schedule 2 is also required if the chemical is a biochemical *(see subparagraph 7(1)(b)(ii) of the Regulations)*. No further information will be required unless: (a) the chemical is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment *(see subsection 7(2) of the Regulations)* or (b) the public may be significantly exposed to the chemical in a product *(see subsection 7(3) of the Regulations)*.

[3] Notification must be sent to the Minister if: the chemical or biochemical is specified on the NDSL following submission of the information to in *subparagraph 8(1)(b)(i) of the Regulations* and item 10 of Schedule 5 *(see subsection 8(2) of the Regulations)*.

[4] Additional information specified in Schedule 2 is also required if the chemical is a biochemical *(see subparagraphs 8(1)(a)(ii), b(ii) and c(ii) of the Regulations)*.

Figure A1-3 Polymers / Biopolymers Other Than Those In Figure A1-1



[1] *Section 10 of the Regulations*.

[2] Additional information specified in Schedule 2 is also required if the polymer is a biopolymer *(see paragraph 10(b) of the Regulations)*.

[3] Not required for Reduced Regulatory Requirement polymers. Also subject to certain exceptions *(see subsection 11(5) of the Regulations)*. Additional information specified in Schedule 2 is also required if the polymer is a biopolymer *(see paragraph 11(1)(b) of the Regulations*. No further information will be required unless: (a) the polymer is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment *(see subsection 11(2) of the Regulations)* or (b) the public may be significantly exposed to the polymer in a product *(see subsection 11(3) of the Regulations)*.

[4] Not required for Reduced Regulatory Requirement polymers. Also subject to certain exceptions *(see subsection 12(3) of the Regulations)*. Additional information specified in Schedule 2 is also required if the polymer is a biopolymer *(see paragraph 12(1)(b) of the Regulations)*.

Appendix 2 - Schedules of Information Under the Regulations

SCHEDULE 1

(*Subsections 2(2) and 5(1) to (4)*)

Information Respecting Chemicals and Biochemicals That Are Research and Development Substances, Contained Site-Limited Intermediate Substances or Contained Export-Only Substances[31]

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-6.html#h-718054

SCHEDULE 2

(*Subsections 2(2), 5(2) to (4) and 6(2) to (4), subparagraphs 7(1)(a)(ii) and (b)(ii) and 8(a)(ii), (b)(ii) and (c)(ii) and paragraphs10(b), 11(1)(b), 12(1)(b), 17(2)(b) and 18(2)(b)*)

Information Respecting Biochemicals and Biopolymers

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-7.html#docCont

SCHEDULE 3

(*Subsection 2(2) and section 6)*

Information Respecting Polymers and Biopolymers That Are Research and Development Substances, Contained Site-Limited Intermediate Substances or Contained Export-Only Substances[32]

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-8.html#docCont

SCHEDULE 4

(*Subsection 2(2), subparagraphs 7(1)(a)(i), 8(a)(i) and 17(2)(c)(i) and paragraph 17(2)(d))*

Information Respecting Other Chemicals and Biochemicals Not on the NDSL (100 kg) or on the NDSL (1 000 kg)

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-9.html#docCont

SCHEDULE 5

[31] See section 4.2 for definition of special categories.
[32] See section 4.2 for definition of special categories.

(*Subsection 2(2), subparagraphs 7(1)(b)(i), 8(b)(i), subsection 16(3), subparagraph 17(2)(c)(i) and paragraph 17(2)(d)*)

Information Respecting Other Chemicals and Biochemicals Not on the NDSL (1 000 kg) or on the NDSL (10 000 kg)

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-10.html#docCont

SCHEDULE 6

(*Subsection 2(2), subparagraph 8(c)(i) and paragraph 17(2)(d)*)

Information Respecting Other Chemicals and Biochemicals Not on the NDSL (10 000 kg)

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-11.html#docCont

SCHEDULE 7

(*Subsection 2(2) and paragraphs 9(a) and (b)*)

Types of Polymers

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-12.html#docCont

SCHEDULE 8

(*Subsection 2(2) and paragraph 9(c)*)

List Of Reactants and their Chemical Abstracts Service Registry Number

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-13.html#docCont

SCHEDULE 9

(*Subsection 2(2), paragraphs 10(a) and 18(2)(c), subparagraph 18(2)(d)(i) and paragraph 18(2)(e)*)

Information Respecting Reduced Regulatory Requirement Polymers and Other Polymers and Biopolymers (1 000 kg)

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-14.html#docCont

SCHEDULE 10

(*Subsection 2(2), paragraph 11(1)(a), subsection 11(5), subparagraph 18(2)(d)(i) and paragraph 18(2)(e)*)

Information Respecting Other Polymers and Biopolymers on the NDSL or All of Whose Reactants Are on the DSL or NDSL (10 000 kg)

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-15.html#docCont

SCHEDULE 11

(*Subsection 2(2), paragraph 12(1)(a), subsection 12(3)*)

Information Respecting Other Polymers and Biopolymers Not on the NDSL (10 000 kg)

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-16.html#docCont

SCHEDULE 12

(*Subsection 2(2)*)

Overview of Information Requirements

https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2005-247/page-17.html#docCont

Appendix 3 - Naming Substances

A3.1 Representing Substances with Well-Defined Structures

A3.1.1 Chemical Name of the Substance

A name must be provided that describes the substance using the Chemical Abstracts Service (CAS) or International Union of Pure and Applied Chemistry (IUPAC) nomenclature. Ambiguous or incomplete names are not appropriate for substance identification or for any subsequent publication on the DSL. Abbreviations, acronyms, laboratory designations, trade names, trademarks, or any trivial names that are not chemically descriptive should not be submitted. Further clarification of the level of specificity required is provided in Table A3-1.

Do not assume that an ambiguous name is adequate simply because there is only one isomer used in a particular industry or because the structure diagram has been provided with the notification.

Commercial dye names should not be used unless they are cross-referred to Colour Index Names in Volume 5 of the *Colour Index*. The *Colour Index* is a reference publication for manufacturers and users of dyes. It is published by the Society of Dyers and Colourists with assistance from the American Association of Textile Chemists and Colorists.

Inorganic substance names should identify all the elements and specify the element ratios. The use of empirical formulae or Stock Numbers is encouraged. Stock Numbers are Roman numerals added parenthetically to indicate the state or states of oxidation.

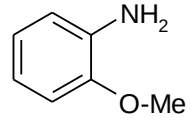
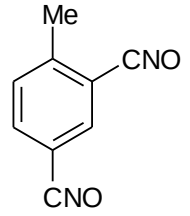
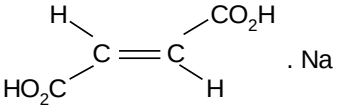
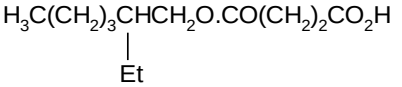
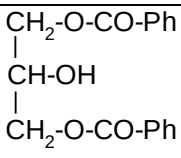
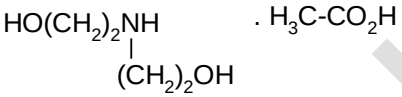
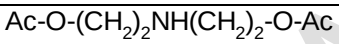
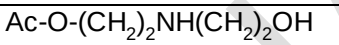
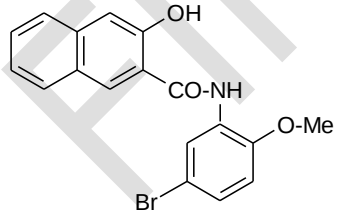
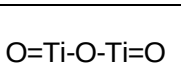
A3.1.2 Molecular Formula

The molecular formula is a summation of the actual numbers and kinds of atoms present in a molecule of a substance. In the case of salts or addition compounds, the molecular formula may be presented as a single summation formula or in the "dot-disconnect" format used by CAS.

Example: Succinic acid, dilithium salt

$LiO_2C(CH_2)_2CO_2Li$		$HO_2C(CH_2)_2CO_2H \cdot 2Li$
$C_4H_4Li_2O_4$	or	$C_4H_6O_4 \cdot 2Li$
(summation)		(dot-disconnect)

Table A3-1 Chemical Names for Well-Defined Substances

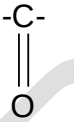
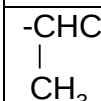
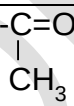
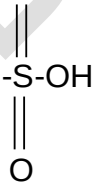
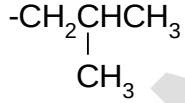
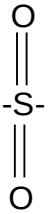
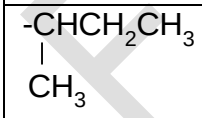
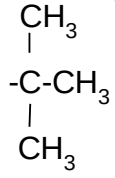
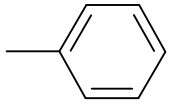
Substance	Unacceptable Name	Acceptable Name
	Anisidine	*o*-Anisidine or 2-Methoxyaniline
	Toluene diisocyanate or TDI	Toluene 2,4-diisocyanate
	Sodium fumarate or Monosodium butenedioate	Monosodium fumarate or Monosodium *trans*-butenedioate or Monosodium *E*-butenedioate
	Octyl succinate or Ethylhexyl succinate	Mono(2-ethylhexyl) succinate
	Glycerol benzoate or Glycerol dibenzoate	Glycerol 1,3-dibenzoate
	Diethanolamine acetate	Diethanolamine acetate salt
	Diethanolamine acetate or Diethanolamine acetate ester	Diethanolamine diacetate ester
	Diethanolamine acetate or Diethanolamine acetate ester	Diethanolamine monoacetate ester
	Blue APM or EMS 17	Brenthol BA or C.I. 37532 or C.I. Azoic Coupling Component 6 or 5'-Bromo-3-hydroxy-2-naphth-*o*-anisidine or *N*-(5-bromo-2-methoxyphenyl)-3-hydroxy-2-naphthalenecarboxamide
	Titanium oxide	Titanium oxide (Ti_2O_3)

A3.1.3 Structural Information

The structure diagram should clearly indicate the identity of the atoms and the nature of the bonds joining them. Guidelines for preparing these diagrams are included in this appendix.

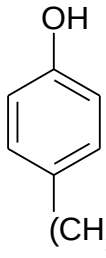
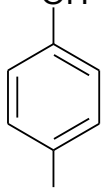
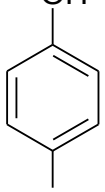
Common abbreviations are acceptable as long as they are unambiguous. Table A3-2 presents examples of abbreviations that may be used.

Table A3-2 Common Abbreviations That Can Be Used to Indicate Structural Information

Structure	Abbreviation	Structure Diagram	Abbreviation
$-CH_3$	Me-		$-CO_2H$
$-CH_2CH_3$	Et-		-CO-
$-(CH_2)_2CH_3$	Pr-	-CH=O	-CHO
	-Pr-*i* or -Pr-*iso*		-Ac
$-(CH_2)_3CH_3$	-Bu		$-SO_3H$
	-Bu-*i* or -Bu-*iso*		$-SO_2-$
	-Bu-*s* or -Bu-*sec*	-N=O	-NO
	-Bu-*t* or -Bu-*tert*		-Ph

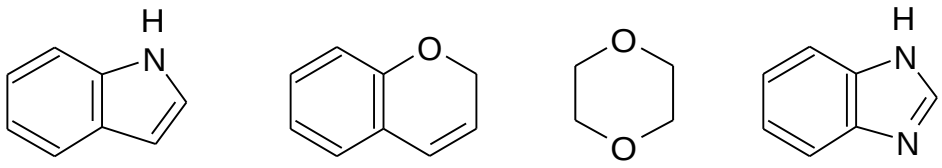
Alkyl groups will be assumed to be normal (linear) unless otherwise designated. If a substance has alkyl groups that are not linear, then the nature of the branching should be described as specifically as possible. Table A3-3 illustrates several different representations for nonylphenol.

Table A3-3 Representations for Nonylphenol

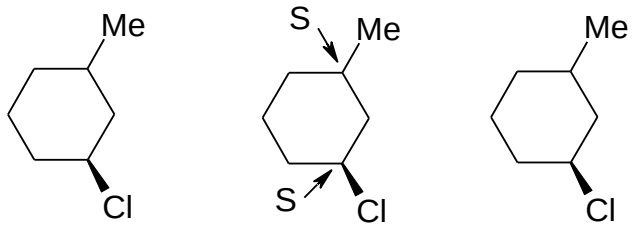
Submitted Name	Structural Representation	CAS registry number	CA Index Name
p-Nonylphenol		104-40-5	Phenol, 4-nonyl-
p-Isononylphenol		26543-97-5	Phenol, 4-isononyl-
Branched, 4-nonylphenol		84852-15-3	Phenol, 4-nonyl-, branched
p-Tripropylene phenol		87247-00-5	Phenol, 4-tripropylene-

Carbon atoms in ring systems and their attached hydrogen atoms need not be explicitly shown.

For example:



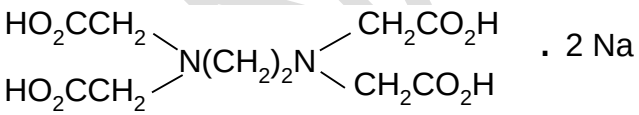
All known stereochemical details should be provided. Indicate whether the stereochemistry is absolute or relative. For example:



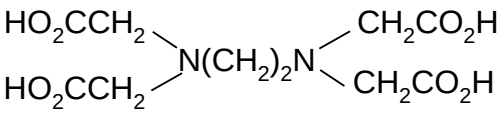
trans (relative) absolute ± (racemic)

The ratio of the components of an addition compound or salt should be clearly indicated if more than one form is theoretically possible. It should also be noted if the ratio is unknown.

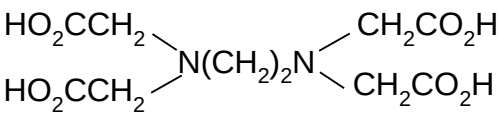
For example:



. 2 Na



. 4 Na



. x Na

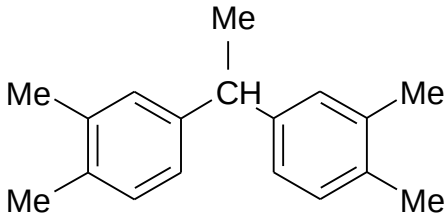
A3.1.3.1 Examples of Well-Defined Substances

The examples that follow illustrate the information necessary to uniquely identify and represent substances with a well-defined structure.

Example 1

Chemical Name of the Substance: *N*-(*s*-Butoxymethyl)acrylamide
Molecular Formula: $C_8H_{15}NO_2$
Structural Information: $H_2C=CH-CO-NH-CH_2-O-Bu\text{-}sec$ ***COMMENT**: Branching of alkyl groups must be indicated or the group will be assumed to be linear. For example, the Bu group on the following diagram would be represented linearly as - $CH_2CH_2CH_2CH_3$* $H_2C=CH-CO-NH-CH_2-O-Bu$

Example 2

Chemical Name of the Substance: 1,1-Di-3,4-xylylethane; 1,1-Bis(3,4-dimethylphenyl)ethane
Molecular Formula: $C_{18}H_{22}$
Structural Information:    ***COMMENT**: The semicolon is used to separate the two names. Both names cite locants. Dixylylethane would not be an appropriate name for this substance.*

Example 3

Chemical Name of the Substance: Sodium sebacate; Sodium decanedioate
Molecular Formula: $C_{10}H_{18}O_4$. x Na
Structural Information: $HO_2C\text{-}(CH_2)_8\text{-}CO_2H$. x Na ***COMMENT**: Use of "x" in the molecular formula and structure diagram clearly indicates that the ratio of the salt is unknown.*

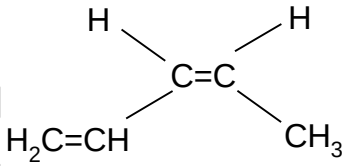
Example 4

Chemical Name of the Substance: Disodium sebacate; Disodium decanedioate
Molecular Formula: $C_{10}H_{18}O_4$. 2 Na
Structural Information: $HO_2C\text{-}(CH_2)_8\text{-}CO_2H$. 2 Na ***COMMENT**: When known, ratios should be cited in the name, formula, and structure. The formula could also be given as $C_{10}H_{16}Na_2O_4$. The structure could also be shown as* $NaO_2C\text{-}(CH_2)_8\text{-}CO_2Na$

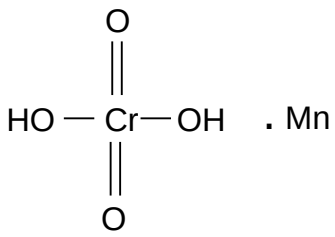
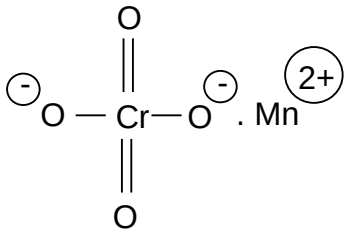
Example 5

Chemical Name of the Substance: 1,3-Pentadiene; Piperylene
Molecular Formula: C_5H_8
Structural Information: $H_2C=CH-CH=CH-CH_3$ ***COMMENT**: Stereochemistry is not cited in the name or structure. See EXAMPLE 6 for a specific stereoisomer.*

Example 6

Chemical Name of the Substance: *cis*-1,3-Pentadiene; *Z*-1,3-Pentadiene; *cis*-Piperylene
Molecular Formula: C_5H_8
Structural Information:    ***COMMENT**: Stereochemistry is cited in both the name and structure. See EXAMPLE 5 for an example of a non-stereospecific substance.*

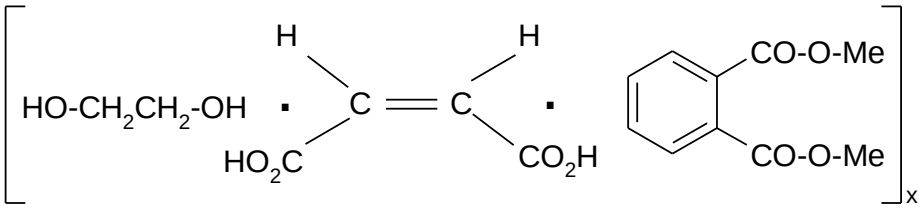
Example 7

Chemical Name of the Substance: Manganese (II) chromate (IV); Manganese chromate ($MnCrO_4$); Chromium manganese oxide ($MnCrO_4$)
Molecular Formula: H_2CrO_4Mn
Structural Information:    ***COMMENT:*** *Stock numbers or empirical formulae should be included in the name when known. The following diagram is also acceptable:* 

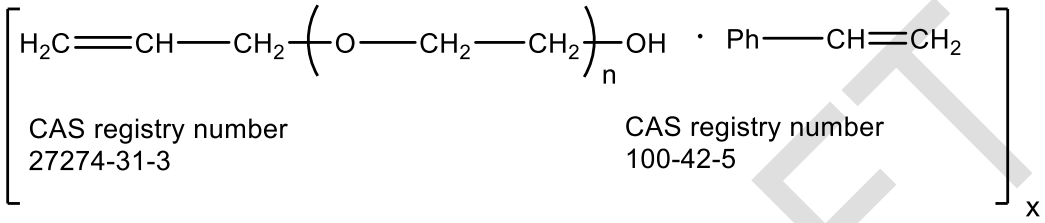
Example 8

Chemical Name of the Substance: PVC; Polyvinyl chloride
Molecular Formula: $(C_2H_3Cl)_x$
Structural Information: $ClCH=CH_2$ + ABIN ⟶ Polyvinyl chloride ***COMMENT**: Polymeric substances are to be described in terms of their starting reactants. Starting reactants are defined as those that become part of the polymer composition. If the role of the reactant ABIN is an initiator, it should not be included in the polymer description appearing on the DSL. ABIN, if placed in commerce, must be reported separately.*

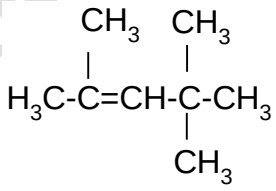
Example 9

Chemical Name of the Substance: Maleic acid-dimethyl phthalate-ethylene glycol copolymer; *cis*-2-Butenedioic acid-dimethyl phthalate-ethylene glycol polymer
Molecular Formula: $(C_2H_6O_2\text{-}C_4H_4O_4\text{-}C_{10}H_{10}O_4)_x$
Structural Information: 

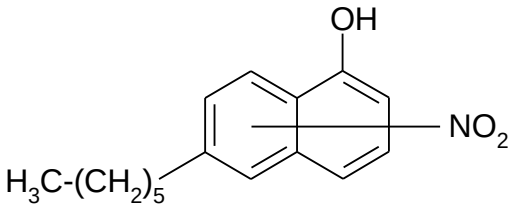
Example 10

Chemical Name of the Substance: Styrene-polyethyleneglycol monoallylether
Molecular Formula: $((C_2H_4O)_nC_3H_6O.C_8H_8)_x$
Structural Information:    ***COMMENT**: Names and CAS registry numbers rather than structure diagrams may be used to describe reactants. Polyglycol derivatives should be represented on the basis of their polymeric structure.*

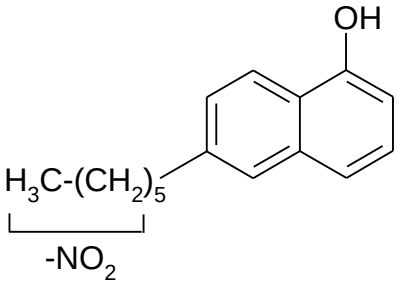
Example 11

Chemical Name of the Substance: 2,4,4-Trimethyl-2-pentene
Molecular Formula: C_8H_{16}
Structural Information:  ***COMMENT**: Isobutylene dimer would not be an appropriate chemical name of the substance for this structure. Designations such as dimer and trimer are appropriate only when the degree of polymerization is a specific value from two through ten but the specific structure is unknown.*

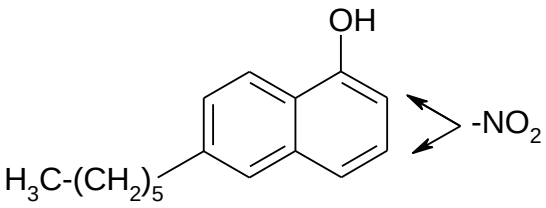
Example 12

Chemical Name of the Substance: ar-Nitro-6-hexyl-1-naphthol; ar-Nitro-6-hexyl-1-hydroxynaphthalene
Molecular Formula: $C_{16}H_{19}NO_3$
Structural Information:    ***COMMENT**: Compare to EXAMPLES 13 and 14. The structural representation should represent all known specificity.*

Example 13

Chemical Name of the Substance: 6-(Nitrohexyl)-1-naphthol; 6-(Nitrohexyl)-1-hydroxynaphthalene
Molecular Formula: $C_{16}H_{19}NO_3$
Structural Information:    ***COMMENT**: Compare to EXAMPLES 12 and 14. The structural representation should represent all known specificity.*

Example 14

Chemical Name of the Substance: 2 or 3-Nitro-6-hexyl-1-naphthol; 2 or 3-Nitro-6-hexyl-1-hydroxynaphthalene
Molecular Formula: $C_{16}H_{19}NO_3$
Structural Information:    ***COMMENT**: Compare to EXAMPLES 12 and 13. The structural representation should represent all known specificity.*

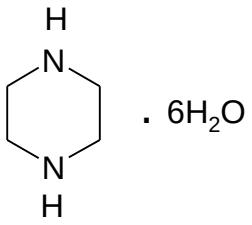
Example 15

Chemical Name of the Substance: Aluminum nickel
Molecular Formula: Ni_3Al
Structural Information: Ni_3Al ***COMMENT**: Known stoichiometry should be indicated. Ni-Al would be unacceptable.*

Example 16

Chemical Name of the Substance: Synthetic geikielite
Molecular Formula: $Mg\text{-}O_3Ti$
Structural Information: ***COMMENT**: Synthetic minerals should indicate in the Chemical Name of the Substance that they are synthetic.*

Example 17

Chemical Name of the Substance: Piperazine hexahydrate; Arpezine
Molecular Formula: $C_4H_{10}N_2 \cdot 6H_2O$
Structural Information:  ***COMMENT**: Substances that are described as hydrates should be represented as the anhydrous form.*

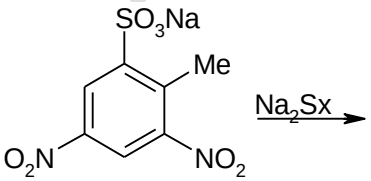
A3.2 Representing Substances That Are Complex and Variable

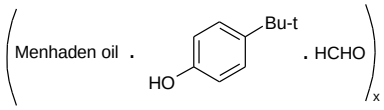
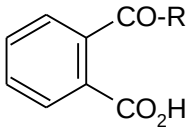
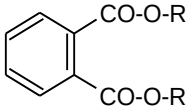
Substances that cannot be represented by a complete structure diagram and specific molecular formula are known as substances of Unknown or Variable composition Complex reaction products or Biological materials (UVCBs).

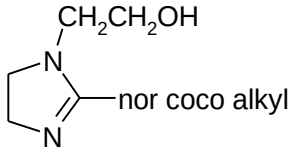
A3.2.1 Chemical Name of the Substance

The Guidelines for names for UVCB substances are similar to the instructions given in section 1.3.1 of this Appendix for Well-Defined Substances and should be reviewed for additional information. See Table A3-4 for further clarification of the level of specificity required.

Table A3-4 Chemical Names for Complex and Variable Substances

Substance	Unacceptable Name	Acceptable Name
	RGP Brown or Sodium dinitrotoluenesulfonic acid polysulfide	C.I. Sulphur Brown 42 or C.I. 53030 or Thionone Brown R0 or Sodium 3,5-dinitro-*o*-toluenesulfonic acid reaction product with sodium polysulfide

$H_2C=CH-R$ bromination / chlorination R = C_{10-28} Alkyl	Halogenated C_{12-30} α-alkenes or Bromo and chloroalkenes	C_{12-30} α-alkenes bromo and chloro derivs. or C_{12-30} α-(alkenes, brominated and chlorinated) or Alkenes, C_{12-30} α-brominated and chlorinated
	Fish oil-butyl phenol-formaldehyde resin or Marine oil, *p-tert*-butylphenol, formaldehyde resin or Menhaden oil, 4-butylphenol, formaldehyde resin	Menhaden oil, *p-tert*-butylphenol, formaldehyde resin
Linseed oil fatty acids . xNa	Vegetable fatty acids sodium salts or Linseed sodium salts or Linseed oil sodium salts	Linseed oil fatty acids sodium salts or Fatty acids, linseed-oil, sodium salts
 R = C_{8-10} branched alkyl	Nonyl phthalate or Isononyl phthalate or Mono-C_{8-10}-alkyl phthalate	Mono-C_{8-10}-branched alkyl phthalate or 1,2-Benzenedicarboxylic acid, mono-C_{8-10}-branched alkyl esters
 R = C_{8-10} branched alkyl	Dinonyl phthalate or Diisononyl phthalate or Di-C_{8-10}-alkyl phthalate	Di-C_{8-10}-branched alkyl phthalate or 1,2-Benzenedicarboxylic acid, di-C_{8-10}-branched alkyl esters
Coconut oil fatty acids + salt formation HOCH $CH_2NHCH_2CH_2OH$	Coconut oil fatty acids reaction product with diethanolamine	Coconut oil fatty acids-diethanolamine salt or Coconut oil fatty acids, compound with diethanolamine or Fatty acids, coco, compds. with diethanolamine
$HOCH_2CH_2NHCH_2CH_2O$-CO-R -CO-R = coco fatty acyl	Coconut oil fatty acids reaction product with diethanolamine	Coconut oil fatty acids diethanolamine monoester or Fatty acids, coco, 2-[[(2-hydroxyethyl)amino]ethyl] esters

	Coconut oil reaction product with aminoethyl ethanolamine or Coco alkylimidazolineethanol	Coconut oil and *N*-(2-aminoethyl)ethanolamine cyclization product or 1*H*-Imidazole-ethanol, 4,5-dihydro-2-norcoco alkyl derivs

A3.2.2 Molecular Formula

Most UVCB substances cannot be represented by a specific molecular formula. However, in some cases, it may be possible to provide a molecular formula that is a summation of the range of numbers and specific kinds of atoms present in a molecule of a substance. Hypothetical or idealized molecular formulae must not be cited.

Molecular formulae for salts and addition compounds, if provided, may be presented as a single summation formula or in the dot-disconnect format used by CAS.

Example: C_{6-12}-alkyldicarboxylic acid, disodium salt

$NaO_2C\text{-}C_{6-12}alkyl\text{-}CO_2Na$ $HO_2C\text{-}C_{6-12}alkyl\text{-}CO_2H \cdot 2Na$

$C_{8-14}H_{12-24}Na_2O_4$ or $C_{8-14}H_{14-26}O_4 \cdot 2Na$

A3.2.3 General Guidelines

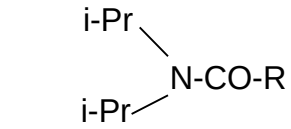
Because, in most cases, a unique structure diagram cannot be provided, descriptive information for the substance, components, or precursors should be given.

If a partial structure diagram can be provided, it should clearly indicate the identity of the atoms and the nature of the bonds joining them. Common abbreviations for substituents and functional groups are acceptable if they are unambiguous. Alkyl groups will be assumed to be normal (linear) unless otherwise designated.

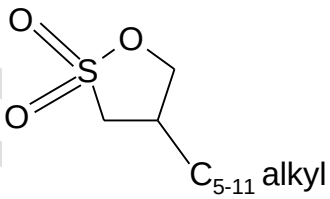
Substance representations should describe all known specificity, such as salt ratios and stereochemical details.

The examples are intended to illustrate the level of specificity that should be provided. It is strongly recommended that the notifier follow the style of the examples.

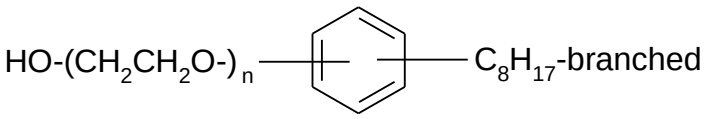
Example 18

Chemical Name of the Substance: *N*,*N*-Diisopropyl tall oil fatty amides
Molecular Formula:
Structural Information:    -CO-R = tall oil fatty acyl ***COMMENT**: A substance can be described using a partial structure diagram.*

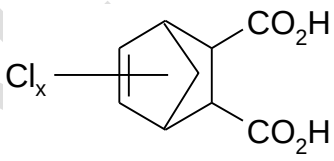
Example 19

Chemical Name of the Substance: 4-(C_{5-11}-alkyl)-1,2-oxathiolane, *S*,*S*-dioxide
Molecular Formula:
Structural Information:    ***COMMENT**: Carbon ranges of alkyl groups must be defined.*

Example 20

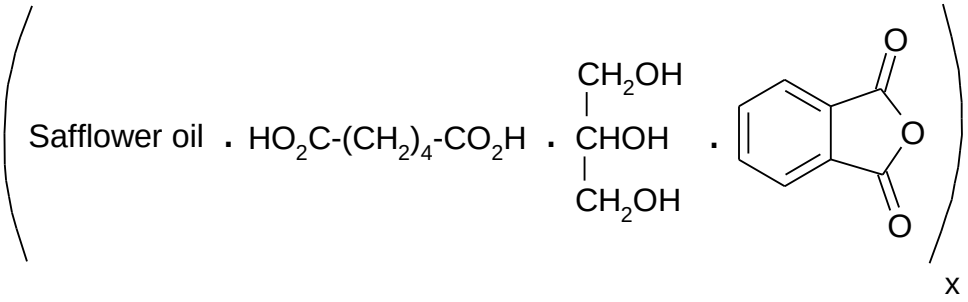
Chemical Name of the Substance: C_8 branched alkylphenol ethoxylate
Molecular Formula:
Structural Information:  ***COMMENT**: Representations should describe all known specificity, including structural information for alkyl groups.*

Example 21

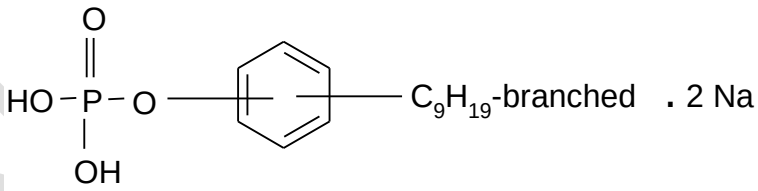
Chemical Name of the Substance: Chlorinated 5-norbornene-2,3-dicarboxylic acid; Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, chloro derivs.
Molecular Formula:
Structural Information: 

Example 22

Chemical Name of the Substance: Safflower oil, polymer with adipic acid, glycerol and phthalic anhydride

Molecular Formula:
Structural Information: 

Example 23

Chemical Name of the Substance: Phosphoric acid, mono(branched nonyl) phenyl ester, disodium salt
Molecular Formula: $C_{15}H_{25}O_4P$. 2 Na
Structural Information: 

A3.2.4 Plant and Animal Products

Complex and variable substances which are produced by chemical modification of naturally occurring products or are separated from them by physical processing[33] must be identified by specifying the genus and species as well as other unambiguous common names of the source.

Do not assume that a common name is adequate simply because there is only one source used in a particular industry. For example, mint oil should not be used to identify Japanese mint oil, Bergamot oil, Spearmint oil, or Peppermint oil. Vegetable oil should not be used to identify corn oil, soybean oil, or linseed oil.

[33] Physical processing includes such methods as: distillation; steam distillation; crystallization; sublimation; salting-out; ion-exchange; and heating for reasons other than to remove water.

The examples are intended to illustrate the level of specificity that should be provided.

Example 24

Chemical Name of the Substance: Soybean fatty acids, diethylenetriamine salt
Molecular Formula:
Structural Information: Soya fatty acids . x $H_2NCH_2CH_2NHCH_2CH_2NH_2$

Example 25

Chemical Name of the Substance: Mixed vegetable oils fatty acids methyl esters
Molecular Formula:
Structural Information: Methyl esters of mixed vegetable oils fatty acids ***COMMENT**: If a substance is obtained from a manufacturing process that used different types of plants to produce an oil, then the term, "mixed vegetable" should be used in the name.*

Example 26

Chemical Name of the Substance: Japanese mint oil; Japanese peppermint oil
Molecular Formula:
Structural Information: Oil extracted from *Mentha arvensis* var. *piperascens* ***COMMENT**: The genus and species of the plant that was processed to produce the oil must be identified.*

Example 27

Chemical Name of the Substance: *Mentha citrata* oil; Bergamot mint oil
Molecular Formula:
Structural Information: Oil extracted from *Mentha citrata* ***COMMENT****: Bergamot oil would not be an appropriate chemical name of the substance because bergamot oil is also extracted from* Citrus bergamia.

Example 28

Chemical Name of the Substance: Acetylated lemongrass oils
Molecular Formula:
Structural Information: Lemongrass oil 8007-02-1* $\xrightarrow{\text{acetylation}}$ ***COMMENT****: The genus and species,* Cymbopogon citratus*, is associated with the CAS registry number 8007-02-1* in the Chemical Definition Section of the* Toxic Substances Control Act *(TSCA).*

Example 29

Chemical Name of the Substance: Terpene-free bergamot oil fraction
Molecular Formula:
Structural Information: Terpene-free fraction distilled from oil extracted from *Citrus bergamia.*

Example 30

Chemical Name of the Substance: Corn oil deodorizer distillate
Molecular Formula:
Structural Information: A complex mixture of fatty acids, sterols, aldehydes, ketones, and other materials prepared by the steam distillation of corn oil followed by condensation of the steam containing these materials.

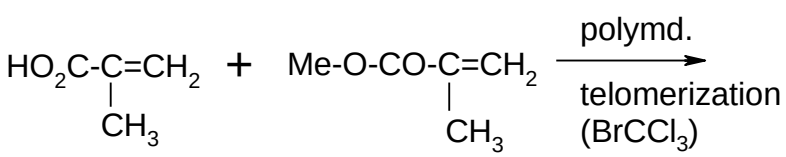
A3.2.5 Reaction Products

The reaction scheme should include the chemical identity of the immediate precursors, the nature of the reaction, and the reactants, whether or not they are implied by the reaction term. Reaction terms should be as specific as possible (e.g., acetylation, alkaline hydrolysis, chlorination, diazotization, epoxidation). General reaction terms such as addition, condensation, and reaction should not be used.

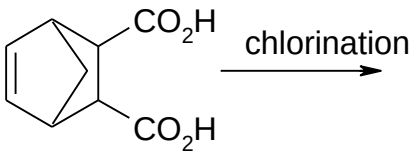
Although the substance itself may be a UVCB substance, the precursors or components may be well-defined substances. Any descriptions provided for well-defined precursors or components should meet the specifications discussed previously.

The examples are intended to illustrate the level of specificity that should be provided.

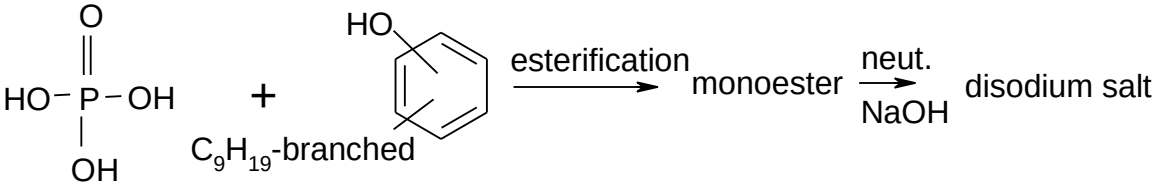
Example 31

Chemical Name of the Substance: Polymer of methyl methacrylate, methacrylic acid, and bromotrichloromethane
Molecular Formula: $(C_4H_6O_2 \cdot C_5H_8O_2)_x \cdot xCBrCl_3$
Structural Information: 

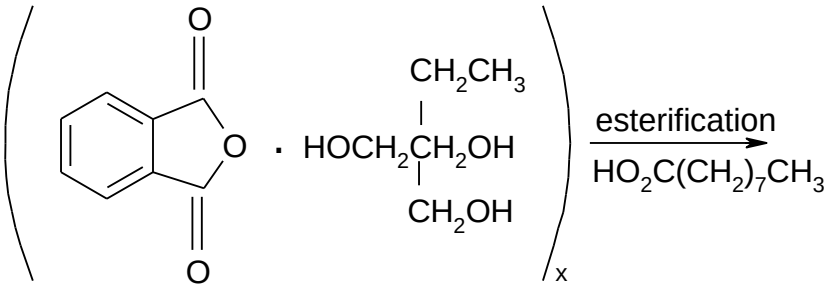
Example 32

Chemical Name of the Substance: Chlorinated 5-norbornene-2,3-dicarboxylic acid; Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, chloroderivs.
Molecular Formula:
Structural Information:  ***COMMENT**: Compare to EXAMPLE 21. Either method is acceptable. Both depict the same degree of specificity.*

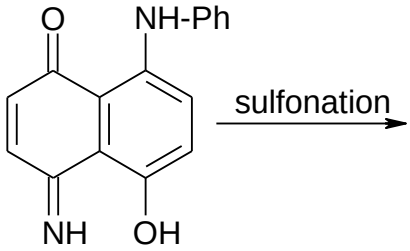
Example 33

Chemical Name of the Substance: Phosphoric acid, mono(branched nonyl) phenyl ester, disodium salt
Molecular Formula:
Structural Information:  ***COMMENT**: Compare to EXAMPLE 23. Either method is acceptable. Both depict the same degree of specificity.*

Example 34

Chemical Name of the Substance: Phthalic anhydride-trimethylolpropane copolymer, pelargonate
Molecular Formula:
Structural Information: 

Example 35

Chemical Name of the Substance: C.I. Acid Black 47; C.I. 56055; Sulfonine Grey G
Molecular Formula:
Structural Information: 

Example 36

Chemical Name of the Substance: Tallow fatty acid ethanolamine amides salt
Molecular Formula:
Structural Information: Tallow fatty acids + $H_2NCH_2CH_2OH \rightarrow$ amides ***COMMENT****: Because tallow fatty acids and ethanolamine may react to form a variety of different products (*e.g., *salts, esters, cyclization products), the product description should be as specific as possible and include typical composition.*

A3.2.6 Products from Industrial Processes

Some complex and variable substances are most conveniently described by text rather than structure diagrams or reaction schemes.

The description should include precursors, method of preparation, process terms (low-boiling, catalytic reformed), physical properties (if known), and typical chemical composition. Specifically, the substance information should describe the substance as uniquely as possible and include (if known)

(a) process description (catalytic cracking, dewaxed, destructive distillation);

(b) carbon (alkyl) range (C_4 through C_{12});

(c) physical properties (boiling range, viscosity, solid, slag, and softening point);

(d) principal chemical composition (hydrocarbons, sulfides, terpenes); and

(e) source (e.g., petroleum, coal).

It is recommended that, whenever appropriate, schematic diagrams (depicting the industrial process and the point where the notified substance is isolated) be provided.

The description should not include process terms that are unqualified or broadly descriptive or undefined trade jargon.

The examples are intended to illustrate the level of specificity that should be provided. Additional examples of the type of descriptive information required can be found in the Chemical Substance Definitions sections of TSCA.

Example 37

Chemical Name of the Substance: C_{9-13} Alkylbenzene distillation residues
Molecular Formula:
Structural Information: Complex residue from the distillation of C_{9-13} alkylbenzenes having a boiling point > 600 °F. Composed primarily of diphenylalkanes, diphenylbenzenes, and diphenyldialkanes. The alkyl groups are linear C_{9-13}.

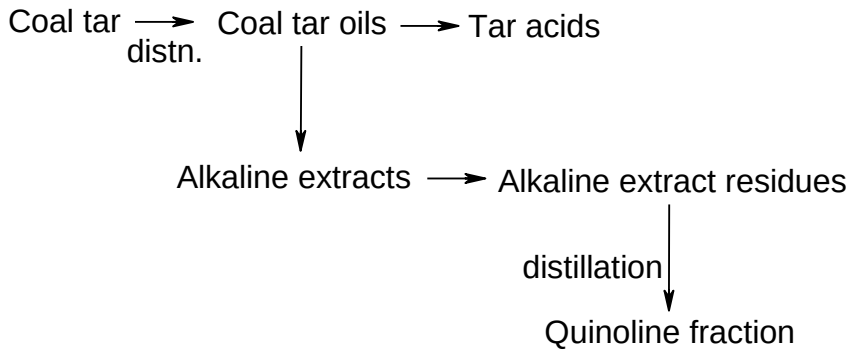
Example 38

Chemical Name of the Substance: Ferrous metals blast furnace slag
Molecular Formula:
Structural Information: Fused substance formed by the action of a flux on the gangue of iron-bearing materials charged to the blast furnace and on oxidized impurities of the iron produced. Composed primarily of sulfur and oxides of Al, Ca, Mg, and Si.

Example 39

Chemical Name of the Substance: Oxidized black liquor; Spent pulping liquor, oxidized
Molecular Formula:
Structural Information: Substance produced by the oxidation of black liquor with pulping chemicals used in Kraft, sulfite, semichemical, or other pulping processes. Composed primarily of partially oxidized ligosulfonates, sugars and hemicelluloses.

Example 40

Chemical Name of the Substance: Quinoline fraction of coal tar alkaline extract residues
Molecular Formula:
Structural Information:    Quinoline fraction consists primarily of quinoline, isoquinoline, methylquinolines, and dimethylquinolines.

Example 41

Chemical Name of the Substance: Coal coke
Molecular Formula:
Structural Information: Carbonaceous residue from the high temperature (> 700 °C) destructive distillation of coal. Composed primarily of carbon but may contain sulfur and ash.

Example 42

Chemical Name of the Substance: Petroleum coke
Molecular Formula:
Structural Information: Carbonaceous residue from the high temperature destructive distillation of petroleum fractions. Composed primarily of carbon but may contain some hydrocarbons with high carbon to hydrogen ratios.

Example 43

Chemical Name of the Substance: Naphtha, petroleum, hydrodesulfurized full-range
Molecular Formula:
Structural Information: A complex combination of hydrocarbons obtained from a catalytic hydrodesulphurization process. It consists of hydrocarbons having carbon numbers predominantly in the range of C_4 through C_{12} and in the boiling range of approximately 30 to 250 °C.

Example 44

Chemical Name of the Substance: Copper smelting slag
Molecular Formula:
Structural Information: Substance resulting from the smelting of copper and previous metals obtained from primary and secondary sources and plant reverts. Composed primarily of iron oxides and SiO_2. May contain Cu, Pb, Ni, and other non-ferrous metals and oxides.

Example 45

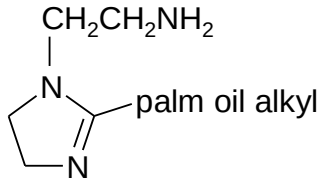
Chemical Name of the Substance: Olivine vanadium blue
Molecular Formula:
Structural Information: An organic pigment formed by the high temperature calcination of vanadium (IV) oxide and silicon oxide in varying amounts. Ionic diffusion occurs to form a crystalline matrix. Alkali or alkaline earth halides may be included as modifiers.

A3.2.7 Combinations of UVCB Substances

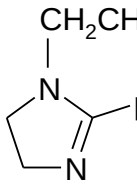
Because of their complexity, precursors, reactants, reaction scheme, and nominated substance should be described as specifically as possible when notifying substances produced by the combination of UVCB substances. It is strongly recommended that before reporting these types of substances all sections of this appendix be carefully reviewed.

The examples are intended to illustrate the level of specificity that should be provided.

Example 46

Chemical Name of the Substance: Palm oil and diethylenetriamine cyclization product, compound with distillation residue
Molecular Formula:
Structural Information:    Residue from distillation of C_{6-18} saturated and unsaturated monobasic acids and C_{8-15} dibasic acids. Consists C_{9-18} saturated dibasic acids salts. May also contain polymers, anhydrides, and polyesters.

Example 47

Chemical Name of the Substance: Palm oil and diethylenetriamine cyclization product compound with oxidized light petroleum distillates
Molecular Formula:
Structural Information:  palm oil alkyl + Oxidized light petroleum distillates → salts 64742-98-9 ***COMMENT**: The use of CAS registry number 64742-98-9 eliminates the need to include a lengthy description of the starting material.*

Example 48

Chemical Name of the Substance: Oxidized sesquiterpene fraction of cedarwood oil
Molecular Formula:
Structural Information: Sesquiterpene fraction distilled from oil extracted from *Cedrus atlantica*, Pinaceae. $\xrightarrow{\text{oxidation}}$

Appendix 4 - Locating Chemical Abstracts Service Registry Numbers

To assist notifiers in their efforts to locate Chemical Abstracts Service Registry Numbers (CAS registry numbers), this appendix describes sources that may be used to identify CAS registry numbers.

A4.1 Chemical Abstracts

Chemical Abstracts (CA) contains abstracts and index entries selected from scientific and technical literature. The weekly issues and volume indexes provide access to the world literature for chemical substances. At present, the Chemical Abstracts Service (CAS) publishes two complete volumes of abstracts and their corresponding indexes for each calendar year. The indexes to each volume include a Formula Index, a Chemical Substance Index, and a General Subject Index. The Formula Index provides CA Index Names, CAS registry numbers, and abstract numbers for chemical substances identified by molecular formula. Entries are arranged according to the Hill System. The Chemical Substance Index links the CA Index Name, which identifies a specific chemical substance, with an abstract number. CA Index names are listed in alphabetical order and CAS registry numbers are given. The General Subject Index links subject terms, such as reactions, classes of substances, and plant and animal species, with their corresponding Abstract Numbers.

A4.1.1 Chemical Abstracts Service Registry Services

Using CAS Registry Services, notifiers can obtain CAS registry numbers for their substances or CA Index Names for confidential substances. This service furnishes CAS registry numbers to customers either by retrieving existing CAS registry numbers and/or assigning new CAS registry numbers for chemical substances that meet CAS criteria for registration.

A4.1.2 Chemical Abstracts Index Guide

To help users of CA Indexes locate substances and other information, CAS publishes the CA Index Guide. The CA Index Guide details the major points of CA indexing policy and provides cross-references, from various subject terms and substance names used in the literature, to the controlled CA indexing terminology and CAS registry numbers, if applicable. For substance identification, this publication provides many cross-references to common names and the CA Index Name and CAS registry number.

A4.1.3 Registry Handbook – Common Names

A microform publication, this handbook is an alphabetical list of common names, CA Index Names, and other related names; associated with each name is the corresponding CAS registry number and molecular formula. There are over 1 250 000 names and 500 000 CAS registry numbers in this publication.

A4.1.4 Registry Handbook – Number Section

This publication, in ascending CAS registry number order, provides CA Index Names and molecular formulae for over seven million substances. The “base book” covers 1965 to 1971. Additions are provided in annual supplements based on specific Registry Number ranges.

A4.1.5 Chemical Abstracts Service ONLINE

The CAS ONLINE is a comprehensive chemical information database that offers substance-oriented and subject-oriented searching. This database makes information about chemical and related disciplines available through three related files: the Registry File for substance identification, the CA File for bibliographic searching, and the CAOLD File for reference to pre-1967 literature. CAS ONLINE is available on Scientific and Technical Information Service International by direct telephone link through most telecommunications networks. The Registry File contains information about more than nine million substances reported in the literature, with more than 10 000 new entries added every week. CAS registry numbers for chemical substances can be identified by searching the Registry File using molecular formulae, substructures, or a variety of chemical dictionary terms such as chemical names or name fragments.

A4.2 Toxic Substances Control Act Chemical Substance Inventory

The *Toxic Substances Control Act* (TSCA) Chemical Substance Inventory of 1985 published by the United States Environmental Protection Agency (US EPA) is an inventory of over 58 000 chemical substances manufactured, imported, or processed in the United States of America. The inventory consists of five volumes that can be used to identify CAS registry numbers.

Volume I is the list, in ascending CAS registry number, of chemical substances submitted in compliance with TSCA. It can be used if the CAS registry number for a substance is known and the submitter wishes to verify that it represents the substance that is being reported. This verification is conducted by reviewing the CA Index or Preferred Name associated with the CAS registry number. It should describe the substance in question precisely. A dagger (†) after the CAS registry number indicates that additional descriptive information necessary for unambiguous identification of the substance is provided in the Chemical Substance Definitions section found in Volume I; this information should be reviewed to ensure accurate verification.

Volumes II and III are the Substance Name section of TSCA and should be used if a substance name is available. This section is an alphabetical listing of chemical names including CA Index or Preferred Names, TSCA submitted chemical names, and CAS synonyms that are associated with the corresponding CAS registry number. Examine the adjacent entries or search for a permutation of the name when a particular name is not found. Numeric and alphabetic prefixes, Roman or Greek letters or numbers used as locants, and alternate spellings (e.g., sulfur and sulphur) and punctuation may affect the alphabetic sequence. The abbreviation C.I. is alphabetized as if it were expanded to *Colour Index*.

It is not uncommon for a single non-systematic name to be associated with two or more different substances. Trademarks, trade names, and names that do not specify locants or ratios are ambiguous. When such a name is located, look for the CAS registry number in Volume I, and review the specific CA Index or Preferred Name associated with that CAS registry number to ensure that the CAS registry number represents the substance that is to be notified.

Volume IV is the Molecular Formula section of TSCA and should be used if the molecular formula of a substance is known. This section lists TSCA substances of known chemical constitution according to the Hill System. Review the name(s) cited below the molecular formula to find the CAS registry number for the substance to be notified. Note that in the Molecular Formula Index, names of chemical salts and molecular addition compounds will, in most cases, be found under the molecular formula of the acid. For example, the substance name “trisodium salt of phosphoric acid” would be found under the molecular formula of the substance name for phosphoric acid (H_3PO_4).

Volume V, which is the Unknown or Variable composition Complex reaction product or Biological material (UVCB) section, should be used if a molecular formula cannot be calculated and an appropriate entry for the substance has not been located in the Name section. This Index is an alphabetic list of Subset Headings with associated CAS registry numbers and CA Preferred Names for substances of UVCBs. Subset Headings identify categories of closely related UVCB substances and provide a method of organizing UVCBs into subsets containing a relatively small number of entries.

A4.3 European Inventory of Existing Commercial Chemical Substances (EINECS)

The European Inventory of Existing Commercial Chemical Substances (EINECS) (the Advance Edition), published by the Commission of the European Communities, is an inventory of more than 100 000 chemical substances that includes substances from the European Core Inventory (ECOIN) that were declared to be on the European Community market between January 1, 1971, and September 18, 1981. This Advance Edition is divided into a Master Inventory and five supplementary Indexes (a Name Index, a Molecular Formula Index, a UVCB Index, a Definition Index, and a Plant Name Index). The Master Inventory is a list of the chemical substances in ascending order according to their EINECS Number and their CAS registry number. It also provides the

chemical name, molecular formula, and substance definition, if appropriate. The Name Index, the Molecular Formula Index, and the UVCB Index are similar to the corresponding indexes that were described for the TSCA Inventory.

A4.4 The Cosmetic, Toiletry and Fragrance Association Cosmetic Ingredient Dictionary

This book, published by the Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), provides nomenclature recommendations for ingredients of formulations used by the cosmetic industry. It is an alphabetical listing of CTFA Adopted Names with associated substance information; this information includes CAS registry numbers, CTFA Recognized Disclosure Numbers, definitions, structures, and related chemical or trade names. CAS registry numbers have been included in the monographs for many of the CTFA Adopted Names and are included in a numerical listing in Section VIII of this dictionary.

A4.5 International Nonproprietary Names for Pharmaceutical Substances

This publication is a computer printout of several lists of International Nonproprietary Names (INN) that are published regularly in the *WHO Chronicle*. It includes the INN in Latin, English, French, Russian, and Spanish and references to the numbers of proposed and recommended lists in which they have been published; it also includes other data such as references to national nonproprietary names, pharmacopoeia monographs, molecular formulae, and CAS registry numbers.

A4.6 Registry of Toxic Effects of Chemical Substances

This publication from the U.S. Department of Health and Human Services is a compendium of toxicity data extracted from the scientific literature and is prepared in compliance with the *Occupational Safety and Health Act* of 1970. The Registry of Toxic Effects of Chemical Substances (RTECS) contains names of different chemicals with their associated toxicity data, synonyms, molecular formula, RTECS Number, and CAS registry number. There is a CAS registry number–RTECS Number Index that permits the reader to look up the RTECS data record of a substance when only its CAS registry number is known.

A4.7 The Merck Index

The Merck Index, published by Merck and Company Inc., is an alphabetical listing of chemicals, drugs, pesticides, and biologically active substances. The monograph for each listing contains substance data such as chemical names, drugs code numbers, literature references, toxicity data, CAS registry numbers, and generic names.

A4.8 United States Adopted Names and the United States Pharmacopeial Convention Dictionary of Drug Names

This publication by the United States Pharmacopeial Convention, Inc. is a dictionary of nonproprietary names, brand names, code designations, and CAS registry numbers for drugs. The names are listed in alphabetical order by INN.

Appendix 5 - Masking of Substance Names

The procedures presented below provide guidance to notifiers submitting a New Substances Notification (NSN) in which they wish to claim the substance identity as confidential. A masked name should also be submitted for publication purposes to list a substance confidentially on the Domestic Substances List (DSL) or the Non-domestic Substances List (NDSL). The intent of masking is to conceal, only to the extent necessary, the explicit chemical name of the substance. Although this appendix illustrates the masking of only single distinctive element, multiple masking is permitted if the notifier can provide justifications (see section 4 of this appendix).

There are inherent differences between explicit chemical name of substances having definite structure diagrams and definite molecular formulas and those that cannot be represented by definite structure diagrams and may or may not be represented by definite molecular formulas. Each of these possibilities is addressed separately as follows.

A5.1 Substances Having Definite Chemical Structure Diagrams and Molecular Formulas

A substance having a definite chemical structure and molecular formula can be represented by a unique structure diagram and unique molecular formula. The explicit chemical name of the substance normally discloses the following structural information:

(a) the identity of the parent structure (i.e., a chain of carbon atoms, a ring system, or a coordinated metal);

(b) the identity, number, and position of chemical group(s) that are attached to the parent structure(s) or to other chemical groups;

(c) the identity and number of cations and counter ions (for salts); and

(d) the stereochemical relationships.

The masked name may be created by disguising structurally descriptive segments of the explicit chemical name of the substance. Masking may be accomplished by replacing distinct elements of the explicit chemical name with non-descriptive terms and/or removing locants. The number of distinctive elements in an explicit chemical name that can be replaced or removed will be limited to the minimum number necessary to ensure confidentiality (excluding the removal of a stereochemical indicator from an explicit chemical name).

The single distinctive elements of an explicit chemical name that may be masked when creating a proposed masked name are

(a) a locant that specifies the placement of a chemical group;

(b) the locant and multiplicative prefix (e.g., di-,tri-, and tetra-) that together specify the number and placement of a given chemical group;

(c) the name of a given chemical group;

(d) the name of a given parent structure, and locants of chemical groups attached to the parent structure; and

(e) the name and multiplicative prefixes (specifying the number) of a given simple cation or anion of a salt.

Table A5-1 lists by name and molecular formula the type of chemical groups that can be masked. The groups of atoms found in Table A5-1 are common structural units; a given group may be listed under more than one name. Each group includes at least one atom other than carbon or hydrogen.

If the substance contains a chemical group that includes a carbon atom having more than a single valence (e.g., carbonyl -CO-), the name of that chemical group cannot be masked if the carbon atom is directly attached to an acyclic carbon atom or is included within a ring system. In this circumstance, only the atom or group of atoms attached to the valence carbon atom can be masked.

Certain chemical groups in Table A5-1 include hydrogen atoms that are often additionally substituted, e.g., an ethyl group may be substituted for a hydrogen of the sulfamyl group (H_2NSO_2-) to give $C_2H_5NHSO_2$-. If additionally substituted, **only** the chemical group listed in Table A5-1 should be masked, **not** the substituent.

Table A5-1 lists most of the common chemical functional groups that contain oxygen, e.g., H_2NCO-. Although not always listed, the Group VIa element (sulfur, selenium, and tellurium) analogs of these functional groups, e.g., H_2NCSe-, are considered included within Table A5-1 and, accordingly, may be used in masking.

Table A5-1 List of Common Chemical Groups

Common Chemical Groups
aldo O=
amidino $H_2NC(=NH)$-
amino H_2N-
(aminoamidino) $H_2NC(=NNH_2)$- or $H_2NNHC(=NH)$-
(aminocarbonyl) H_2NCO-
[(aminocarbonyl)amino] H_2NCONH-
[2-(aminocarbonyl)hydrazino] $H_2NCONHNH$-
[(aminocarbonyl)hydrazono] $H_2NCONHN=$

(aminohydrazonomethyl) $H_2NC(=NNH_2)$-
[(aminohydroxymethylene)hydrazino] $H_2NC(OH)=NNH$-
(aminoiminomethyl) $H_2NC(=NH)$-
(aminoiminophosphoranyl) $H_2NPH(=NH)$-
(*p*-aminophosphinimyl) $H_2NPH(=NH)$-
(aminosulfinyl) H_2NSO-
(aminosulfonyl) H_2NSO_2-
(aminothio) H_2NS-
(aminothioxomethyl) H_2NCS-
ammonio H_3N-
antimono -Sb=Sb-
arseno -As=As-
arsenoso OAs-
arsinico HOAs(O)≡
arsinidene AsH=
arsinidyne As≡
arsinimyl $AsH_2(=NH)$-
arsino AsH_2-
arsinothioyl $AsH_2(S)$-
arsinyl $AsH_2(O)$-
arsinylidene AsH(O)≡
arso O_2As-
arsono $(HO)_2As(O)$-
(arsonooxy) $(HO)_2As(O)O$-
arsononitridyl AsH(=N)-
arsoranyl AsH_4-
arsoranylidyne AsH_2≡
arsylene AsH=
arsylidyne As≡
astato At-
astatoxy O_2At-
astatyl O_2At-
azi -N=N-
azido N_3-
(azidocarbonyl) N_3CO-
(azidofurmyl) N_3CO-
(azidosulfonyl) N_3SO_2-
azino =NN=
azo -N=N-
azoxy -N(O)=N-
bismuthino BiH_2-
bismuthylene BiH=
bismuthylidyne Bi≡

borono $(HO)_2B$-
(boronooxy) $(HO)_2BO$-
boryl BH_2-
borylene BH=
borylidyne B≡
bromo Br-
(bromocarbonyl) BrCO-
(bromoiminomethyl) BrC(=NH)-
(bromosulfonyl) $BrSO_2$-
carbamido H_2NCONH-
carbamoyl H_2NCO-
carbamyl H_2NCO-
carbonimidoyl -C(=NH)=
(carbonimidoylamino) $H_2N=C=N$-
carbonothioyl -CS-
carbonyl -CO-
(carbonylidiimino) -NHCONH-
(carbonyldioxy) -OC(O)O-
carboxy HO_2C-
chloro Cl-
(chlorocarbonyl) ClCO-
(chloroformyl) ClCO-
(chloroiminomethyl) ClC(=NH)-
(chlorosulfinyl) ClSO-
(chlorosulfonyl) $ClSO_2$-
chlorosyl OCl-
(chlorothio) ClS-
chloryl O_2Cl-
cyanato NCO-
cyano NC-
1,2-diarsenediyl -As=As-
diarsenyl HAs=As-
diarsinetetrayl =AsAs=
diarsinyl H_2AsAsH-
1,2-diazenediyl -N=N-
diazeno HN=N-
diazo N_2=
diazoamino -NHN=N-
diazonio N_2^+-
1,2-diborane(4)diylidene =BB=
diborane(4)tetrayl =BB=
digermanylene $-GeH_2GeH_2$-
digermathianyl $H_3GeSGeH_2$-

dioxy -OO-
1,2-diphosphenediyl -P=P-
1,2-diphosphinediyl -PHPH-
1,2-diphosphinediylidene =PP=
diphosphinetetrayl =PP=
diphosphinyl H_2PPH-
diseleno -SeSe-
1,2-disilanediyl -SiH_2SiH_2-
disilanoxy H_3SiSiH_2O-
disilanyl H_3SiSiH_2-
disilanylene -SiH_2SiH_2-
(disilanyloxy) H_3SiSiH_2O-
(disilathianyloxy) $H_3SiSSiH_2O$-
disilazanoxy $H_3SiNHSiH_2O$-
disilazanyl $H_3SiNHSiH_2$-
2-disilazanyl $(H_3Si)_2N$-
(disilazanyloxy) $H_3SiNHSiH_2O$-
1,3-disiloxanediyl -SiH_2OSiH_2-
1,3-disiloxanediylidene =SiHOSiH=
disiloxanoxy $H_3SiOSiH_2O$-
disiloxanylene -SiH_2OSiH_2-
(disiloxanyloxy) $H_3SiOSiH_2O$
disilthianoxy $H_3SiSSiH_2O$-
1,2-distannanediyl -SnH_2SnH_2
distannanylene -SnH_2SnH_2-
1,3-distannathianediylidene =SnHSSnH=
1,2-distibenediyl -Sb=Sb-
disulfinyl -S(O)S(O)-
dithio -SS-
(dithiocarboxy) HSCS-
(dithiohydroperoxy) HSS-
epidioxy -OO-
epidiseleno -SeSe-
epidithio -SS-
epioxy -O-
episeleno -Se-
epithio -S-
epoxy -O-
fluoro F-
(fluorocarbonyl) FCO-
fluoryl O_2F-
formamido HCONH-
1,5-formazanidyl -N=NCH=NNH-

1-formazano $H_2NN=CHN=N-$
5-formazano HN=NCH=NNH-
formazanyl $HN=NC(=NNH_2)-$
formimidoyl HC(=NH)-
formyl HCO-
(formylamino) HCONH-
germanetetrayl =Ge=
germyl H_3Ge-
germylene $H_2Ge=$
germylidyne HGe≡
guanyl $H_2NC(=NH)-$
hydrazi -NHNH-
1,2-hydrazinediylidene =NN=
hydrazino H_2NNH-
(hydrazinocarbonyl) $H_2NNHCO-$
(hydrazinoiminomethyl) $H_2NNHC(=NH)-$
(hydrazinosulfinyl) $H_2NNHSO-$
(hydrazinosulfonyl) H_2NNHSO_2-
(hydrazinothioxomethyl) $H_2NNHCS-$
1-hydrazinyl-2-ylidene -NHN=
hydrazo -NHNH-
hydrazono $H_2NN=$
hydroperoxy HOO-
(hydroperoxycarbonyl) HOOCO-
(hydroperoxyiminomethyl) HOOC(=NH)-
(hydroperoxysulfinyl) HOOS(=O)-
(hydroperoxysulfonyl) $HOOS(=O)_2-$
(hydroperoxythioxomethyl) HOOCS-
hydroxy HO-
(hydroxyamino) HONH-
(hydroxyimino) HON=
(hydroxyiminomethyl) HOC(=NH)-
hydroxyl HO-
(hydroxyphosphinyl) HOPH(O)-
imidocarbonyl -C(=NH)-
(imidocarbonylamino) HN=C=N-
imino HN=
(iminomercaptomethyl) HSC(=NH)-
[imino(mercaptooxy)methyl] HSOC(=NH)-
(iminomethyl) HN=CH-
(iminonitrilo) -NHN=
(iminophosphoranyl) $H_2P(=NH)-$

(iminosulfenomethyl) HOSC(=NH)-
iodo I-
(iodocarbonyl) ICO-
iodosyl OI-
iodyl O_2I-
isocyanato OCN-
(isocyanatocarbonyl) OCNCO-
(isocyanatosulfonyl) $OCNSO_2$-
isocyano CN-
(isocyanocarbonyl) CNCO-
isonitro HON(O)=
isonitroso HON=
isosemicarbazido $H_2NC(OH)=NNH$-
isothiocyanato SCN-
(isothiocyanatocarbonyl) SCNCO-
(isothiocyanatosulfonyl) $SCNSO_2$-
isothiocyano SCN-
Keto O=
mercapto HS-
(mercaptoamino) HSNH-
(mercaptooxy) HSO-
[(mercaptooxy)carbonyl] HSOCO-
[(mercaptooxy)sulfinyl] $HSOS(=O)$-
[(mercaptooxy)sulfonyl] $HSOS(=O)_2$-
[(mercaptooxy)thioxomethyl] HSOCS-
(mercaptotelluro) HSTe-
nitramino O_2NNH-
aci-nitramino HON(O)=N-
nitrilio $HN^+\equiv$
nitrilo N≡
(nitrilophosphoranyl) HP(=N)-
nitro O_2N-
acinitro HON(O)=
(nitroamino) O_2NNH-
(aci-nitroamino) HON(O)=N-
(nitrooxy) O_2NO-
nitroso ON-
(nitrosoamino) ONNH-
(nitrosoimino) ONN=
(nitrosooxy) ONO-
(nitrothio) O_2NS-

oximido HON=
oxo O=
(oxoboryl) OB-
oxy -O-
1,3-pentazadienyl $H_2NN=NN=N$-
perchloryl O_3Cl-
perseleno Se=Se=
perthio S=S=
phosphinico HOP(O)=
phosphinidene HO=
phosphinidyne P=
phosphinimyl $H_2P(=NH)$-
phosphino H_2P-
phosphinothioyl $H_2P(S)$-
phosphinothioylidene HP(S)=
phosphinyl $H_2P(O)$-
phosphinylidene HP(O)=
phosphinylidyne P(O)=
phospho O_2P-
phosphono $(HO)_2P(O)$-
(phosphonocarbonyl) $(HO)_2P(CO)$
phosphononitridyl HP(=N)-
(phosphonooxy) $(HO)_2P(O)O$-
phosphoranyl H_4P-
phosphoranylidene H_3P=
phosphoranylidyne $H_2P\equiv$
phosphoro -P=P-
phosphoroso OP-
plumbanetetrayl =Pb=
plumbyl H_3Pb-
plumbylene H_2Pb=
plumbylidyne HPb=
seleneno HOSe-
selenino HOSe(O)-
seleninoselenoyl Se=Se=
seleninyl OSe=
seleno -Se-
selenocyanato NCSe-
selenono (HO)SeO2-
selenonyl O_2Se=
selenoxo Se=
selenyl HSe-
semicarbazido $H_2NCONHNH$-

semicarbazono $H_2NCONHN=$
silanetetrayl =Si=
silyl H_3Si-
silylene $H_2Si=$
silylidyne $HSi\equiv$
(silyloxy) H_3SiO-
stannanetetrayl =Sn=
stannono HOSn(O)-
stannyl H_3Sn-
stannylene $H_2Sn=$
stannylidyne $HSn\equiv$
stibinico HOSb(O)=
stibino H_2Sb-
stibo O_2Sb-
stibono $(HO)_2Sb(O)-$
(stibonooxy) $(HO)_2Sb(O)O-$
stiboso OSb-
stibyl H_2Sb-
stibylene HSb=
stibylidyne $Sb\equiv$
sulfamino $HOSO_2NH-$
sulfamoyl H_2NSO_2-
sulfamyl H_2NSO_2-
sulfeno HOS-
(sulfenocarbonyl) HOSCO-
(sulfenosulfinyl) HOSS(=O)-
(sulfenosulfonyl) $HOSS(=O)_2-$
(sulfenothioxomethyl) HOSCS-
sulfhydryl HS-
sulfinimidoyl HN=S=
sulfino HOS(O)
(sulfinooxy) HOS(O)O-
sulfinothioyl S=S=
sulfinyl OS=
sulfo HO_3S-
(sulfoamino) $HOSO_2NH-$
sulfonimidoyl HN=S(O)=
sulfonodiimidoyl $(HN=)_2S=$
sulfonyl $-SO_2-$
(sulfooxy) HO_3SO-
sulfuryl $-SO_2-$
telluro -Te-
telluroxo Te=
telluryl HTe-

1,4-tetraphosphinediyl -$(PH)_4$-
1,7-tetrasiloxanediyl -$SiH_2(OSiH_2)_2OSiH_2$-
tetrathio -SSSS-
1,4-tetrazanediyl -$(NH)_4$-
1,4-tetrazanediylidene =$N(NH)_2N$=
1-tetrazenyl H_2NNHN=N-
thio -S-
(thioarsenoso) S=As-
(thiocarbamoyl) H_2NCS-
thiocarbamyl H_2NCS-
(thiocarbonyl) -CS-
(thiocarboxy) HOSC-
thiocyanato NCS-
thiocyano NCS-
(thioformyl) HCS-
thiohydroperoxy HOS- or HSO-
(thiohydroxy) HS-
(thionitroso) SN-
thionyl -SO-
(thioseleneno) HSSe-
(thiosulfeno) HSS-
(thiosulfo) (HO_2S_2)-
thioxo S=
(thioxoarsino) S=As-
(thioxomethyl) HCS-
thiuram H_2NCS-
triazanyl H_2NNHNH-
1-triazene-1,3-diyl -NHN=N-
1-triazenyl H_2NN=N-
triseleno -SeSeSe-
1,3-trisilanediyl -$(SiH_2)_3$-
1,3,5-trisiloxanetriyl -$SiH(OSiH_2-)_2$
trithio -SSS-
uramino H_2NCONH-
ureido H_2NCONH-
ureylene -NHCONH-

A5.1.1 Parent Masking

The name of a parent structure of a substance that can be described with a definite structure diagram and definite molecular formula may be masked in the explicit chemical name only by the following non-descriptive terms:

alkyl **or** alkane
alkenyl **or** alkene

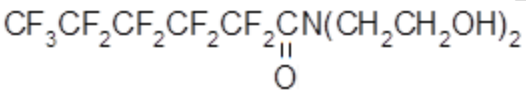
alkynyl **or** alkyne
carbomonocyclic **or** carbomonocycle (e.g., benzene, cyclopentane)
carbopolycyclic **or** carbopolycycle (e.g., naphthalene, spiroundecane)
heteromonocyclic **or** heteromonocycle (e.g., pyrrole, *p*-dioxane)
heteropolycyclic **or** heteropolycycle (e.g., indole, benzothiazole)

In the case of a coordinated metal compound, the identity of the metal atom may be masked by the term “metal” in the explicit chemical name.

Only one such parent group or multiple occurrences of the same parent group should be masked.

The following examples show common explicit chemical names for which a single distinctive element is masked.

Example 1



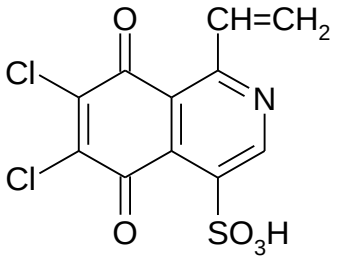
Fully Defined Explicit Chemical Name

2,2,3,3,4,4,5,5,6,6,6-undecafluoro-**N**,**N**-bis(2-hydroxyethyl) hexanamide

Acceptable Single Masking

- fluorine atoms masked:
  2,2,3,3,4,4,5,5,6,6,6-undecahalo-**N**,**N**-bis(2-hydroxyethyl) hexanamide
- locants and multiplicative prefix of fluorine atoms masked:
  polyfluoro-**N**,**N**-bis(2-hydroxyethyl) hexanamide
- hydroxyl groups masked:
  2,2,3,3,4,4,5,5,6,6,6-undecafluoro-**N**,**N**-bis(2-substituted ethyl) hexanamide
- hexane parent (plus locants of chemical groups) masked:
  undecafluoro-**N**,**N**-bis(2-hydroxyethyl) alkanamide
- amide group (plus nitrogen locants) masked:
  2,2,3,3,4,4,5,5,6,6,6-undecafluoro-bis(2-hydroxyethyl) hexane derivative

Example 2



Fully Defined Explicit Chemical Name

6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dioxo-4-isoquinolinesulfonic acid

Acceptable Single Masking

- chlorine atoms masked:

  6,7-dihalo-1-ethenyl-5,8-dihydro-5,8-dioxo-4-isoquinolinesulfonic acid

- vinyl group masked:

  6,7-dichloro-1-alkenyl-5,8-dihydro-5,8-dioxo-4-isoquinolinesulfonic acid

- oxo group masked:

  6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-disubstituted-4-isoquinoline sulfonic acid

- sulfo group masked:

  6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dioxo-4-substituted isoquinoline

- isoquinoline ring (plus locants of chemical groups attached to isoquinoline) masked:

  dichloro-ethenyl-dihydro-dioxo heteropolycyclic sulfonic acid or dichloro-ethenyl-dihydro-dioxo sulfo-heteropolycycle

A5.2 Substances Not Having Definite Structure Diagrams and Molecular Formulas

Some substances such as polymers cannot be represented by definite structure diagrams and may or may not have definite molecular formulas. In other instances the composition can be described only in terms of a complex combination of several different known or unknown components such as Unknown or Variable composition Complex reaction product or Biological material (UVCBs).

The method of manufacture can also identify a substance. For a substance manufactured by means of a chemical reaction, identification can be stated in terms of the immediate precursor substances and other reactants that participate in the final reaction sequence used to manufacture the substance, and the nature of the reaction (e.g., ethoxylation or bromination). For a substance obtained from a source without chemical reaction, processing information identifies the source and method of preparation (e.g., distillation, or extraction with methylene chloride).

Although the explicit chemical name of a substance lacking a definite chemical structure

or unique structure diagram may be based on variable types of descriptive terms, the procedures of masking are similar to those used for substances with definite structure diagrams and definite molecular formulas (see section 1 of Appendix 5).

The composition of a substance that can be represented by a partial or incomplete chemical structure diagram can generally be described by a common chemical name that encompasses the variability or incompleteness in the structure. A masked name for such a substance will usually be acceptable if masking the partial structure diagram follows the same procedures used for substances with definite structure diagrams and definite molecular formulas.

In other instances, the explicit chemical name may identify a predominant component or components of its composition, an immediate precursor or precursors, and other reactants by specific chemical name. A proposed masked name will usually be acceptable for such a substance if it is constructed by masking the chemical name of one such component, precursor, or reactant.

Clearly, the masking procedures in this appendix are most useful for masking the identity of substances having a single distinctive element, and will only be useful for some types of substances that cannot be described with a unique structure diagram. In some of these latter cases, the masking procedures provided may have little applicability. For consistency, submitters must base their choice of a masked name on an explicit chemical name of the substance established in accordance with the current chemical nomenclature rules of IUPAC or CAS,[34] as provided on the new substances submission form (e.g., New Substances Notification (NSN) Form, DSL Nomination Form, NDSL Nomination Form, etc.). The New Substances (NS) program will consider each such proposed masked name on a case-by-case basis.

Example 3

Substance Description

Linseed-oil fatty acids-fumaric acid-glycerol-maleic anhydride polymer

Specific Explicit Chemical Name

Fatty acids, linseed-oil, polymers with fumaric acid, glycerol and maleic anhydride

Acceptable Single Masking

- linseed-oil masked:

  Fatty acids, plant-based oil, polymers with fumaric acid, glycerol and maleic anhydride

- fumaric acid masked:

  Fatty acids, linseed-oil, polymers with alkenedioic acid, glycerol and maleic anhydride

[34] CAS Nomenclature is considered to be any CAS-approved names (e.g., CA Index Name, CAS Synonyms or Inventory name).

Example 4

Substance Description

Polyethylene glycol, mono-C_{12-15}-alkyl ethers, phosphates, potassium salts

Specific Explicit Chemical Name

Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{12-15}-alkyl ethers, phosphates, potassium salts

Acceptable Masked Names

- potassium masked:

  Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{12-15}-alkyl ethers, phosphates, metal salts

- C_{12-15}-alkyl group masked:

  Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, monoalkyl ethers, phosphates, potassium salts

- Ethane masked:

  Poly(oxy-alkanediyl), α-hydro-ω-hydroxy-, mono-C_{12-15}-alkyl ethers, phosphates, potassium salts

A5.3 Masking of Biochemicals and Biopolymers

Biochemicals and biopolymers that do not have catalytic activity can be masked by disguising descriptive segments of the explicit chemical name. Masking of more than one segment of the explicit chemical name is considered multiple masking and would not be permitted without justification. Masking may be accomplished by replacing single distinctive elements of the explicit biological name of a substance with non-descriptive terms and/or removing the locants (see sections 1 and 2 of this appendix).

A5.3.1 Enzymatic Substances

For enzymes, masked names should be created by disguising the fourth level Enzyme Commission number and using the corresponding description of the selected Enzyme Commission level as the disguising term. Removal of each number of the Enzyme Commission number (a.b.c.d.) is a single masking. For example, removing “d” is single masking; removing “c.d” is double masking and “b.c.d” is triple masking. Note that the first number “a” is not maskable. In instances where a fourth level Enzyme Commission number only consists of one entry, the New Substances program will accept reverting to the second level Enzyme Commission number.

Example 5

Substance Description

6-Hydroxynicotinate reductase Enzyme Commission number 1.3.7.1

Proposed double masking

Substituted-heteromonocycle reductase Enzyme Commission number 1.3

Example 6

Substance Description

Chemical Abstracts Service Registry Number (CAS registry number) 9042-64-2: Aromatic-L-amino-acid decarboxylase
Associated Enzyme Commission number: 4.1.1.28

Proposed single masking

Decarboxy-Lyase
Associated Enzyme Commission number: 4.1.1

Example 7

Substance Description

CAS registry number 341585-05-5: Xylose isomerase (Enzyme Commission number 5.3.1.5) (*Lactococcus lactis lactis* strain IL1403 gene xylA) (9CI)

Proposed single masking

Xylose isomerase (Enzyme Commission number 5.3.1.5) (*Lactococcus lactis lactis* gene xylA)

Proposed double masking

Xylose isomerase (Enzyme Commission number 5.3.1.5) (*Lactococcus lactis lactis*)

Proposed triple masking

Intramolecular oxidoreductase (Enzyme Commission number 5.3) (*Lactococcus lactis lactis* strain IL1403)

A5.4 Justifying the Use of Additional Masking

If strict application of the masking procedures (e.g., the masking of only one single distinctive element) would not adequately mask a specific substance identity, then the notifier may propose a masked name that disguises the substance identity to a greater extent. However, such additional masking must be substantiated in a written statement accompanying the masked name request and should be prepared as follows:

(a) Generate the masked name in accordance with the *Masked Name Regulations* following the described procedures.

(b) For the masked name constructed in (a), using a stepwise approach, justify how each additional masking is necessary to disguise the explicit chemical name of the substance identity. For example, a single masking reveals information about the chemical structure that could adversely affect the intellectual property or market value of the substance, so a second masking is required to protect the information. The notifier must clearly explain why each additional masking is required.

Notifiers may propose generally up to five extra masking terms, provided that a justification is given for each additional masking. The first masking term does not require justification; the confidentiality substantiation is sufficient.

Appendix 6 - Examples of Waiver Requests

The requirement to provide test data on a chemical or polymer may be waived if, in the opinion of the Minister of the Environment (the Minister), one of the three statutory criteria for a waiver of information is being met (see section 8.7).

Conditions for accepting a waiver request will be considered on a case-by-case basis. All waiver requests should be accompanied by a well-documented scientific rationale Failure to provide proper rationales, with supporting documentation, will result in the rejection of the waiver request.

Examples of conditions under which waivers may be granted by the Minister are described below. Unless specified otherwise, the examples are in accordance with paragraph 81(8)(*c*) of the *Canadian Environmental Protection Act, 1999* (the Act).

A6.1 Chemicals

The following are examples of circumstances under which the Minister may grant waivers, which may apply to any test:

- The substance is created *in situ* during the manufacturing process and decomposes during isolation attempts.
- The substance coexists with another component or components that cannot be feasibly isolated and that adversely affects test results.
- The substance reacts dangerously during the performance of the test.

A6.1.1 Physico-chemical Endpoints

A6.1.1.1 Melting Point and Boiling Point

The following is an example of conditions under which waivers may be granted by the Minister:

- The substance is a salt that is stable only as an aqueous solution.

Waivers are not required when:

- The substance has a melting point < -25 °C or > 300 °C. A statement to that effect is sufficient to address the melting point requirement.
- The substance has a boiling point < -50 °C or > 300 °C. A statement to that effect is sufficient to address the boiling point requirement.
- The substance undergoes a chemical reaction other than melting or boiling (e.g., degradation, rearrangement). However, the temperature of the chemical reaction must be reported.

When applicable and available, alternative data such as a decomposition point, pour point, softening point or sublimation point can be reported as alternative data.

A6.1.1.2 Density

Waivers are not required when

- the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density would be sufficient.

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested under paragraph 81(8)(*c*) of the Act for the determination of density, on the basis that the notified substance cannot be isolated and it is technically infeasible to determine the density.

A6.1.1.3 Vapour Pressure

The following are examples of conditions under which waivers may be granted by the Minister:

- The substance has a large molecular weight (> 1000 Da).
- The substance is an ionic solid.
- The substance is a solid with a high melting point (> 300 °C).

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested under paragraph 81(8)(*a*) of the Act for the determination of vapour pressure on the basis that the substance is an ionic solid and therefore has negligible vapour pressure.

Waivers are not required when

- the substance has a standard boiling point < 0 °C. A statement to that effect is sufficient to address this requirement.

A6.1.1.4 Water Solubility

The following is an example of conditions under which waivers may be granted by the Minister:

- The substance forms a stable emulsion in water which cannot be separated by filtration or centrifugation methods (e.g., surface active substances).

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested under paragraph 81(8)(*c*) of the Act on the basis that the notified substance reacts dangerously during performance of the test.

Waivers are not required when

- the substance is 100% miscible in water (> 1000 g/L, as per the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 105); or
- the substance is produced in an aqueous solution and is not available in an isolated form. A statement to that effect is sufficient to address this requirement.

A6.1.1.5 Octanol/Water Partition Coefficient

The following are examples of conditions under which waivers may be granted by the Minister:

- The substance is inorganic (i.e., does not contain any carbon atoms).
- The solubility of the substance in water and/or octanol cannot be measured quantitatively.
- The substance is surface active (surface tension of < 60 mN/m, as prescribed in OECD TG 115).

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested under paragraph 81(8)(*c*) of the Act for the determination of octanol/water partition coefficient on the basis that it was technically infeasible to determine this endpoint using OECD 107 and 117 TGs owing to the surface active (surface tension of < 60 mN/m) nature of the notified substance.

Waivers are not required when

- the substance has a water solubility > 5 g/L. A statement to that effect is sufficient to address this requirement.

A6.1.1.6 Ready Biodegradation

The following is an example of conditions under which waivers may be granted by the Minister:

- The substance is inorganic (i.e., contains no carbon atoms).

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested under paragraph 81(8)(*a*) of the Act for biodegradation on the basis that the notified substance contains no carbon atoms and is therefore not susceptible to biodegradation.

A6.1.1.7 Adsorption–Desorption

The following is an example of conditions under which waivers may be granted by the Minister:

- The solubility of the substance in water cannot be measured quantitatively.

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested under paragraph 81(8)(*c*) of the Act for the determination of adsorption-desorption on the basis that the water solubility for the notified substance could not be determined because the substance cannot be measured quantitatively.

Waivers are not required when

- the substance has a water solubility < 200 µg/L. A statement to that effect is sufficient to address this requirement.

A6.1.1.8 Hydrolysis Rate as a Function of pH

The following is an example of conditions under which waivers may be granted by the Minister:

- The substance has no readily hydrolysable groups and therefore is not expected to hydrolyze. The following provides examples of non-hydrolysable groups.

Alcohols	Glycols
Aldehydes	Halogenated aromatics
Alkanes	Heterocyclic polycyclic aromatic hydrocarbons
Alkenes	Hydrocarbons
Alkynes	Ketones
Aromatic amines	Phenols
Aromatic nitro compounds	Polycyclic aromatic hydrocarbons
Benzenes/Biphenyls	Sulphonic acids
Carboxylic acids	Ethers

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested under paragraph 81(8)(*a*) of the Act for the determination of hydrolysis rate as a function of pH on the basis that the substance does not contain any readily hydrolysable groups and is expected to be stable.

Waivers are not required when

- the substance has a water solubility < 200 µg/L. A statement to that effect is sufficient to address this requirement.

A6.1.2 Toxicological Endpoints

A6.1.2.1 Acute Mammalian Toxicity

The following are examples of conditions under which waivers may be granted by the Minister:

- The substance is corrosive and is expected to cause severe and enduring pain to the test animal. This waiver must be requested under paragraph 81(8)(*a*) of the Act.
- It is not technically feasible to administer known doses of the substance because of its chemical or physical properties. This waiver must be requested under paragraph 81(8)(*c*) of the Act.

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested for acute dermal toxicity under paragraph 81(8)(*a*) of the Act on the basis that the notified substance is corrosive or severely irritating to

the skin of laboratory animals as shown in at least one animal test or has a pH less than 2 or greater than 11.5.

If the vapour pressure of the notified substance is very high and, as such, oral or dermal exposure is not considered to be a significant route of exposure, an inhalation test should be submitted instead. High vapour pressure alone does not necessarily support a waiver request.

A6.1.2.2 Skin Irritation

The following are examples of conditions under which waivers may be granted by the Minister:

- It is not technically feasible to administer the substance topically. The waiver must be requested under paragraph 81(8)(*c*) of the Act.
- The substance is expected to be corrosive to the skin of test animals or has demonstrated high acute dermal toxicity. This waiver must be requested under paragraph 81(8)(*a*) of the Act.

A6.1.2.3 Skin Sensitization

The following is an example of a condition under which a waiver may be granted by the Minister:

- It is not technically feasible to administer the substance topically. The waiver can be requested under paragraph 81(8)(*c*) of the Act.

A6.1.2.4 Repeated-Dose Mammalian Toxicity

The following is an example of a condition under which a waiver may be granted by the Minister:

- It is not technically feasible to administer known doses of the substance because of its chemical or physical properties. This waiver could be requested under paragraph 81(8)(*c*) of the Act.

If the vapour pressure of the notified substance is very high and, as such, oral or dermal exposure is not considered to be a significant route of exposure, an inhalation exposure test should be submitted instead. High vapour pressure alone does not necessarily support a waiver request.

A6.1.2.5 *In Vitro* Test for Gene Mutations

The following is an example of a condition under which a waiver may be granted by the Minister:

- An *in vivo* mammalian genotoxicity assay indicates that the substance has mutagenic activity. This waiver could be requested under paragraph 81(8)(*a*) of the Act.

A6.1.2.6 *In Vitro* Mammalian Test for Chromosomal Aberrations

The following is an example of a condition under which a waiver may be granted by the Minister:

- An *in vivo* mammalian genotoxicity test indicates that the substance has clastogenic activity. This waiver could be requested under paragraph 81(8)(*a*) of the Act.

A6.1.2.7 *In Vivo* Mammalian Test for Genotoxicity

A waiver could be requested under paragraph 81(8)(*a*) of the Act for the determination of *in vivo* genotoxicity on the basis that the following conditions are met in relation to the substance:

- the intended use of the substance will not involve direct, repeated, or prolonged public exposure; and
- the results of both the *in vitro* gene mutation and the *in vitro* mammalian chromosomal aberration tests indicate that the substance has no genotoxic activity in those tests; and
- the chemical structure of the substance, or part thereof, is not related to a known mutagen or carcinogen.

Alternatively, a waiver could be requested under paragraph 81(8)(*a*) of the Act for the determination of *in vivo* genotoxicity on the basis that the two *in vitro* genotoxicity tests (one gene mutation in bacteria and one mammalian chromosomal aberration study) were positive. This waiver will result in the conclusion that the substance is genotoxic.

A6.2 Polymers

The following are examples of conditions under which the Minister may grant waivers, which may apply to any test:

- The substance is created *in situ* during the manufacturing process and decomposes during isolation attempts.
- The substance reacts dangerously during the performance of the test.

A6.2.1 Physico-chemical Endpoints

A6.2.1.1 Number Average Molecular Weight and Concentration/Amount of Residual/Low Molecular Weight Constituents

The following are examples of conditions under which waivers may be granted by the Minister:

- The substance is a highly cross-linked polymer such that the test is not technically feasible (accompanied with a sound scientific justification).
- The substance is insoluble in solvents required to perform Gel Permeation Chromatography (GPC) analysis and no other technique is practicable.

A6.2.1.2 Octanol/Water Partition Coefficient

In cases of water-reactive polymers, the New Substances (NS) program recognizes there may be issues with self-condensation and the formation of precipitates. See Appendix 9 of this Guidance Document for information on the NS program approach to water-reactive polymers.

The following are examples of conditions under which waivers may be granted by the Minister:

- The solubility of the substance in water and/or octanol cannot be measured analytically.
- The substance is surface active (surface tension of < 60 mN/m, as prescribed in OECD TG 115).

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested under paragraph 81(8)(*c*) of the Act for the determination of the octanol/water partition coefficient on the basis that it was technically infeasible to determine this endpoint using OECD 107 and 117 TGs owing to the surface active (surface tension of < 60 mN/m) nature of the notified substance.

A6.2.1.3 Hydrolysis Rate as a Function of pH

In cases of water-reactive polymers, the NS program recognizes there may be issues with self-condensation and the formation of precipitates. See Appendix 10 of this Guidance Document for information on the NS program approach to water-reactive polymers.

The following is an example of a condition under which a waiver may be granted by the Minister:

- The polymer has no readily hydrolysable groups and therefore is not expected to hydrolyse. The following provides examples of non-hydrolysable groups.

Alcohols	Glycols
Aldehydes	Halogenated aromatics
Alkanes	Heterocyclic polycyclic aromatic hydrocarbons
Alkenes	Hydrocarbons
Alkynes	Ketones
Aromatic amines	Phenols
Aromatic nitro compounds	Polycyclic aromatic hydrocarbons
Benzenes/Biphenyls	Sulphonic acids
Carboxylic acids	Ethers

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested under paragraph 81(8)(*a*) of the Act for the determination of hydrolysis rate as a function of pH on the basis that the substance does not contain any hydrolysable groups and is expected to be stable.

Waivers are not required when
- the substance has a water extractability ≤ 2%. A statement to that effect is sufficient to address this requirement.

A6.2.1.4 Ready Biodegradation

In cases of water-reactive polymers, the NS program recognizes there may be issues with self-condensation and the formation of precipitates. See Appendix 10 of this Guidance Document for information on the NS program approach to water-reactive polymers.

The following is an example of a condition under which a waiver may be granted by the Minister:
- The polymer is inorganic (i.e., contains no carbon atoms).

A typical request may be formulated as follows, accompanied by a sound scientific rationale:
- A waiver is requested under paragraph 81(8)(*a*) of the Act for biodegradation on the basis that the notified substance contains no carbon atoms and is therefore not susceptible to biodegradation.

Waivers are not required when
- the substance has a water extractability ≤ 2% at pH 7 or is a branched silicone or siloxane polymer. A statement to that effect is sufficient to address this requirement.

A6.2.2 Toxicological Endpoints

Mammalian toxicity data can potentially be waived for Non-reduced Regulatory Requirement polymers (non-RRR) solely due to the presence of the following cationic or potentially cationic groups: primary, secondary, tertiary amine groups, carbodiimides or sulphoniums. This will be dependent upon, for example, considerations of use patterns and low anticipated potential exposure to the general population. This waiver must be requested under paragraph 81(8)(*a*) of the Act.

Polymers with intended use in personal care products, children’s toys or intended for use in direct food contact materials will generally not be eligible for a waiver of acute and repeated dose toxicity tests if prolonged dermal contact or oral ingestion is expected to be a significant route of exposure.

Polymers will generally not be eligible for a waiver of acute and repeated dose toxicity tests if inhalation is expected to be the most significant route of exposure of the general population based on expected type of use.

A typical request may be formulated as follows, accompanied by a sound scientific rationale:

- A waiver is requested under paragraph 81(8)(*a*) of the Act for 28-day repeated-dose mammalian toxicity on the basis that the notified substance meets the cationic class definition and use patterns of the substance will not involve direct, repeated or prolonged public exposure.

Health toxicity endpoints referred to in item 4 of Schedule 10 of the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) and items 5 to 10 of Schedule 11 of the Regulations are not required if the polymer is a non-RRR polymer solely due to the presence of any of the following functional groups:

a) aldehydes whose functional group equivalent weight (FGEW, see section 3.3.1.8) is less than or equal to 1 000 daltons;
b) vinyl ethers whose FGEW is less than or equal to 5 000 daltons; or
c) sulphonic acids whose FGEW is less than or equal to 5 000 daltons.

A6.2.2.1 Acute Mammalian Toxicity

The following are examples of conditions under which waivers may be granted by the Minister:

- The polymer is corrosive to the skin of test animals and is expected to cause severe and enduring pain to the test animal. This waiver could be requested under paragraph 81(8)(*a*) of the Act.
- It is not technically feasible to administer known doses of the polymer because of its chemical or physical properties. This waiver request can be requested under paragraph 81(8)(*c*) of the Act.

A6.2.2.2 Skin Irritation

The following are examples of conditions under which waivers may be granted by the Minister:

- It is not technically feasible to administer the polymer topically. This waiver request can be requested under paragraph 81(8)(*c*) of the Act.
- The polymer is expected to be corrosive the skin of test animals or has demonstrated high acute dermal toxicity. This waiver could be requested under paragraph 81(8)(*a*) of the Act.

A6.2.2.3 Skin Sensitization

The following is an example of a condition under which a waiver may be granted by the Minister:

- It is not technically feasible to administer the polymer topically. The waiver can be requested under paragraph 81(8)(*c*) of the Act.

A6.2.2.4 Repeated-Dose Mammalian Toxicity

The following is an example of a condition under which a waiver may be granted by the Minister:

- It is not technically feasible to administer known doses of the polymer because of its chemical or physical properties. This waiver could be requested under paragraph 81(8)(*c*) of the Act.

A6.2.2.5 *In Vitro* Test for Gene Mutations

The following is an example of a condition under which a waiver may be granted by the Minister:

- An *in vivo* mammalian genotoxicity test indicates that the polymer has mutagenic activity. This waiver could be requested under paragraph 81(8)(*a*) of the Act.

A6.2.2.6 *In Vitro* Mammalian Test for Chromosomal Aberrations

The following is an example of a condition under which a waiver may be granted by the Minister:

- An *in vivo* mammalian genotoxicity test indicates that the polymer has clastogenic activity. This waiver could be requested under paragraph 81(8)(*a*) of the Act.

A6.2.2.7 *In Vivo* Mammalian Test for Genotoxicity

A waiver may be requested under paragraph 81(8)(*a*) of the Act for the determination of *in vivo* genotoxicity on the basis that the following conditions are met in relation to the polymer:

- the intended use of the polymer will not involve direct, repeated, or prolonged public exposure; and
- the results of both the *in vitro* gene mutation and the in vitro mammalian chromosomal aberration tests indicate that the polymer has no genotoxic activity in those tests; and
- the chemical structure of the polymer, or part thereof, is not related to a known mutagen or carcinogen.

A waiver may be also requested under paragraph 81(8)*(a*) of the Act for the determination of *in vivo* genotoxicity on the basis that the two *in vitro* genotoxicity tests (one gene mutation in bacteria and one mammalian chromosomal aberration study) were positive. This waiver will result in the substance to be concluded as genotoxic.

Appendix 7 – Fulfilling Number Average Molecular Weight Requirements with Gel Permeation Chromatography Data

A7.1 Test Procedures

The test procedures used to generate the number average molecular weight (M_n) data requirements must be specified. The New Substances (NS) program recommends test protocols of the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 118 for the determination of the M_n using Gel Permeation Chromatography (GPC), and OECD TG 119 for residual constituents with molecular weights less than 500 daltons and less than 1 000 daltons.

A7.2 Gel Permeation Chromatogram

A chromatogram with the calculated M_n must be provided.

The name of the notified substance must be clearly identified on the GPC test data. The full original GPC curve must be provided, with the integration interval clearly identified. If the integration does not cover the entire curve, a rationale identifying the excluded parts has to be provided.

A blank run should also be provided.

In the case of GPC curves where a portion has been cut off (that is, not integrated over the full peak area) a justification explaining why certain peaks were not included in the calculation of M_n and percentage of low molecular weight components must be provided. This may involve identification of the cut-off peaks as, for example, residual monomer or additives or other solvents found in the sample.

The name of the test and the calibration curve referenced must be clearly identified on the print-out of the chromatogram. A lab-assigned sample identification code must be identified as the new substance somewhere in the notification. Figure A7-1 is an example of GPC chromatograph with recommended description.

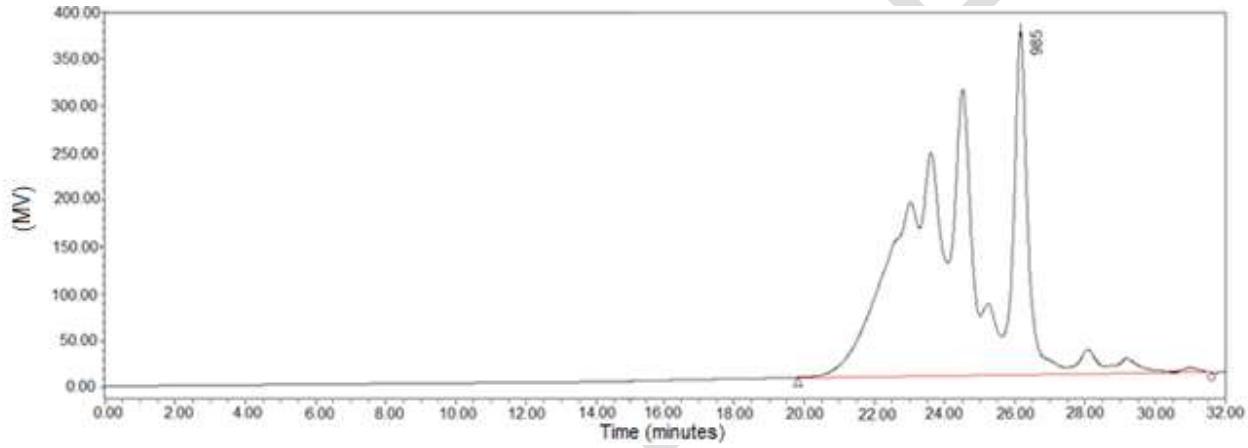
Figure A7-1 Example of GPC chromatogram (mV vs retention time in minutes) and summary table

Sample Name: Trade Name1, reference should match trade names or substance name provided in the New Substances Notification (NSN)
Injection Volume: 100.00

Instrument: Reference to procedure and instrument used
Mobile Phase: Reference to procedure and mobile phase information

Project Name: GPC of Trade Name

Column set: Reference to procedure and column settings output from software
Date Processed: 02/02/2019 11:00:00 AM EDT



	Sample Name	MP[a]	Mn[b]	Mz[c]	Mw[d]	% less than 500	% less than 1000	Mw/Mn Polydispersity
1	Trade Name1	985	1584	4994	3068	3.8	17.4	1.9

[a]MP – molecular weight of the highest peak
[b]M_n – number average molecular weight
[c]M_z – z average molecular weight
[d]M_w – weight average molecular weight

A7.3 Calibration

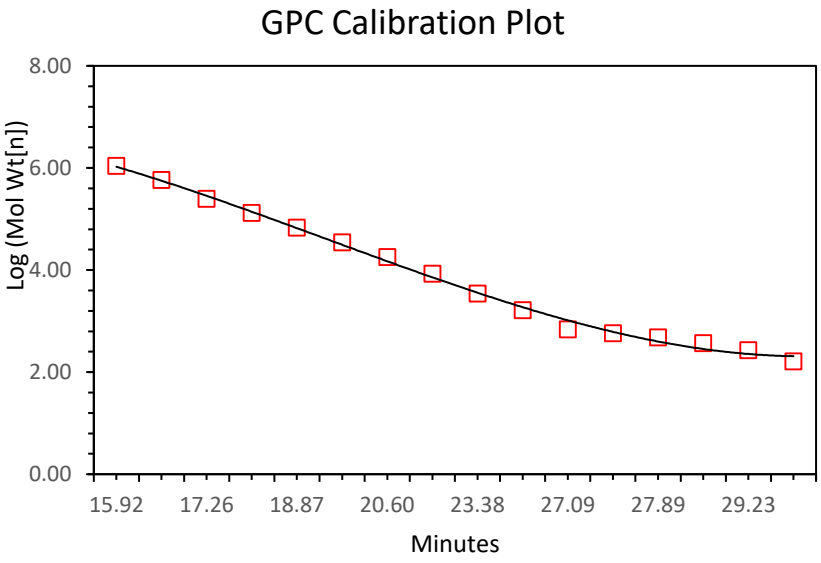
The calibration must identify all running conditions and the type of standards used. The date of calibration should be within one month of the GPC data for the notified substance.

All measurements used for constructing the calibration curves have to be documented, preferably in a table. Figure A7-2 is an example of a calibration curve with a recommended description.

Multi Angle Light Scattering (MALS) or Multi Angle Laser Light Scattering (MALLS) produces absolute molecular weight information and therefore does not require calibration with standards.

Figure A7-2 Examples of GPC calibration plots (Log Mol Wt vs retention time in minutes) of polystyrene standards

Date Processed: 02/01/2019 10:00:00 AM EDT
Instrument: Instrument information
Mobile Phase: Reference to procedure and mobile phase
Column set: Reference to procedure and column settings
Sample: Reference to procedure and sample information
Computer: computer information
The calibration was established with polystyrene standards



GPC Calibration Table

	Mol Wt (daltons)	Retention Time (min)	Calculated Weight (daltons)	% Residual
1	1090000	15,923	1054689	3,348
2	579000	16,456	590573	-1,960
3	246000	17,259	262182	-6,172
4	130000	18,035	127883	1,656
5	67000	18,866	63238	5,949
6	34800	19,630	34981	-0,516
7	17800	20,595	17732	0,381
8	8400	21,751	8577	-2,062
9	3420	23,382	3519	-2,825
10	1620	25,073	1578	2,632
11	682	27,094	665	2,628
12	578	27,455	572	1,053
13	474	27,893	477	-0,623
14	370	28,445	379	-2,346
15	266	29,229	272	-2,180
16	162	30,441	159	1,700

A7.4 Slice Tables

Slice tables are not explicitly mentioned as a mandatory requirement in the regulations. However, they may be required to prove the polymer status or the notification status (Reduced Regulatory Requirement or Non-reduced Regulatory Requirement polymer, see section 3.3.1.5).

Slice information should be acquired at reasonable intervals. Depending on the dispersity of the polymer, one to three pages of information should be enough. Retention time or retention volume should be used as slice-defining parameter.

If supplied, slice tables data must match the GPC curve. Molecular weight at a certain time (or volume) must correspond to the curve.

Slice tables must include a minimum of three columns: retention time (or volume), molecular weight, and the cumulative percent (or similar). Figure A7-3 is an example of slice table with recommended description.

Figure A7-3 Examples of slice tables reporting Slice MW molecular weight and Cumulative %percent

Sample Name: Trade Name1
Date Acquired: 01/31/2019 11:00:00 AM EDT
Date Processed: 02/02/2019 11:00:00 AM EDT

GPC Slice Table

Retention time	Molecular weight	Cumulative %
21.24	11729	1
21.91	7802	5
22.31	6197	10
22.61	5268	15
22.87	4590	20
23.09	4096	25
23.32	3630	30
23.53	3270	35
23.70	3008	40
23.92	2698	45
24.23	2327	50
24.42	2129	55
24.55	2003	60
24.70	1863	65
25.13	1541	70
25.81	1143	75
26.06	1026	80
26.09	1015	81
26.11	1005	82
26.13	996	83
26.17	978	85
26.30	926	90
26.92	714	95
27.17	513	96
28.13	432	97
28.77	330	98
29.41	252	99
31.59	92	100

A7.5 Reporting

The OECD TGs 118 and 119 specify which information to report. Most of the information has been addressed in connection with the mandatory data element it

pertains to and can be covered by ensuring that it is included in the description or machine print-outs.

By submitting these essentials only, reporting on the actual test performance (e.g., treatment of the sample, observations or problems) is often omitted.

The following information should be submitted for assessment:

a) An identification and description of the test guideline and methodology employed, except when OECD TG 118 or 119 are used without modification. Modifications to the testing procedures must be described in detail;
b) Available information about the composition of the test substance and its purity (identity, additives, impurities);
c) Preparation and pre-treatment procedures of the sample before submission to the testing laboratory;
d) A description of the sample preparation, and any observations or problems encountered during the GPC analysis;
e) An evaluation of the presence of undissolved particles, if any;
f) Column type and all other technical relevant information about the instrumentation;
g) Solvent and its purity;
h) Information about all extrapolations, assumptions and approximations made during calibration and experimentation; and
i) Any other information and observations relevant for the interpretation of the results.

A7.6 Frequently Encountered Difficulties

A7.6.1 Limited solubility of the sample

Dissolution should be attempted in at least three different solvents. If it is reasonably successful, select the attempt with the highest solubility and report the amount undissolved. If all attempts to dissolve the substance in GPC-suitable solvents fail, an alternate method may be necessary.

A7.6.2 Artifacts in the chromatogram

If these same artifacts can be shown in a blank or test marker run, they can be excluded from integration.

A7.6.3 Alternative information

Alternative information is accepted on a case-by-case basis. For a polymer that is being salted, the GPC for the non-salted version is acceptable. The same applies to polymers that are being end-capped.

A7.6.4 Calibration date differs drastically from the date of the sample run

If general procedures are in place to confirm the accuracy of the GPC column and instrumentation with a few standards before each run, they should be mentioned in the Test Method description.

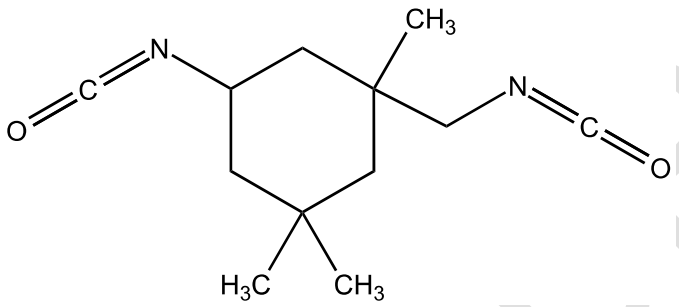
Appendix 8 - Reaction Scheme Requirements

A reaction scheme showing a detailed description of the process by which the notified substance is made is required for Reduced Regulatory Requirement (RRR) polymers (see section 3.3.1.5).

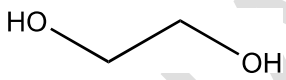
A8.1 Reaction Scheme Examples

These two examples illustrate how the regulatory status of a polymer can be affected by changes in the order of the monomers and their molar ratios. The same three monomers are for the synthesis of both polymers:

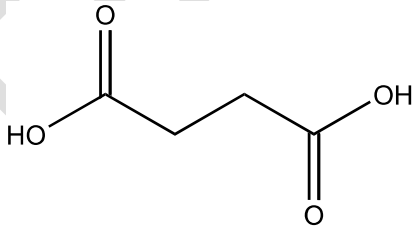
A) Isophorone diisocyanate



B) Ethylene glycol

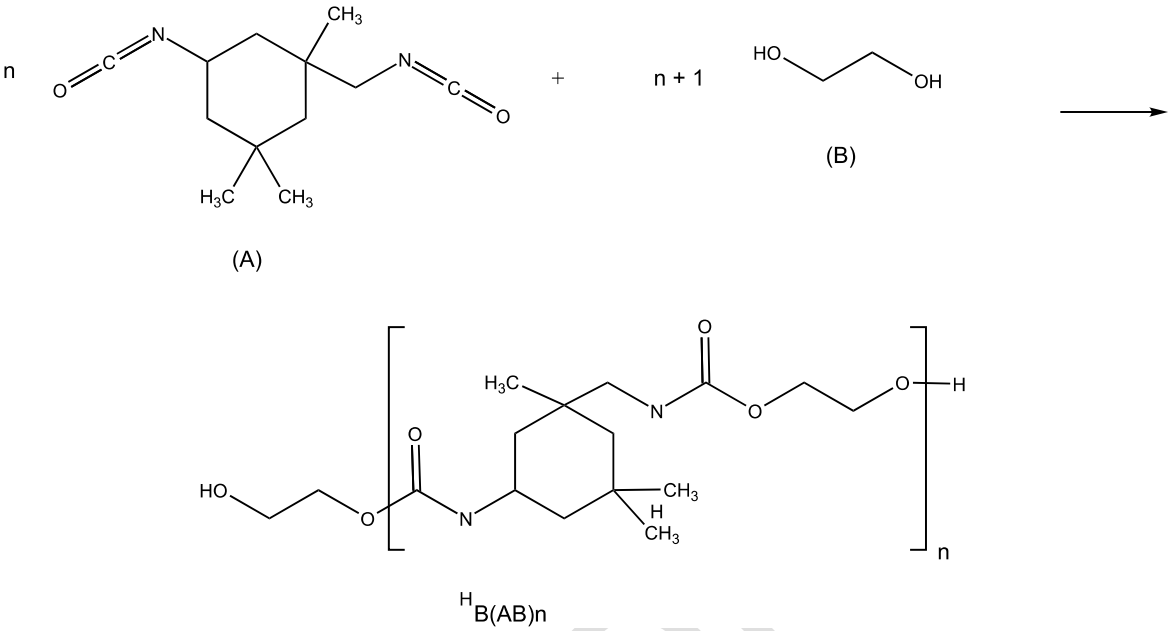


C) 1,4-butanedioic acid

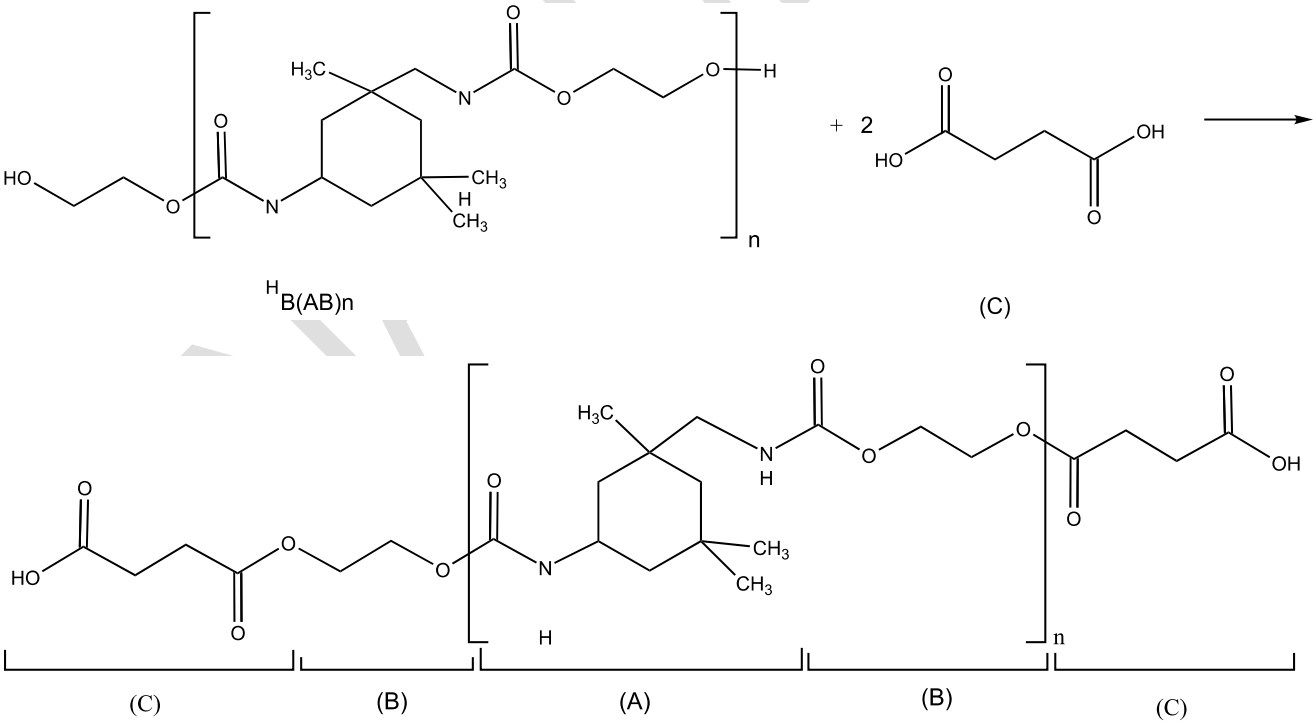


Example 1 – The reaction scheme to obtain Polymer 1 is as follows.

STEP 1 – Polyurethane formation



STEP 2 – Esterification

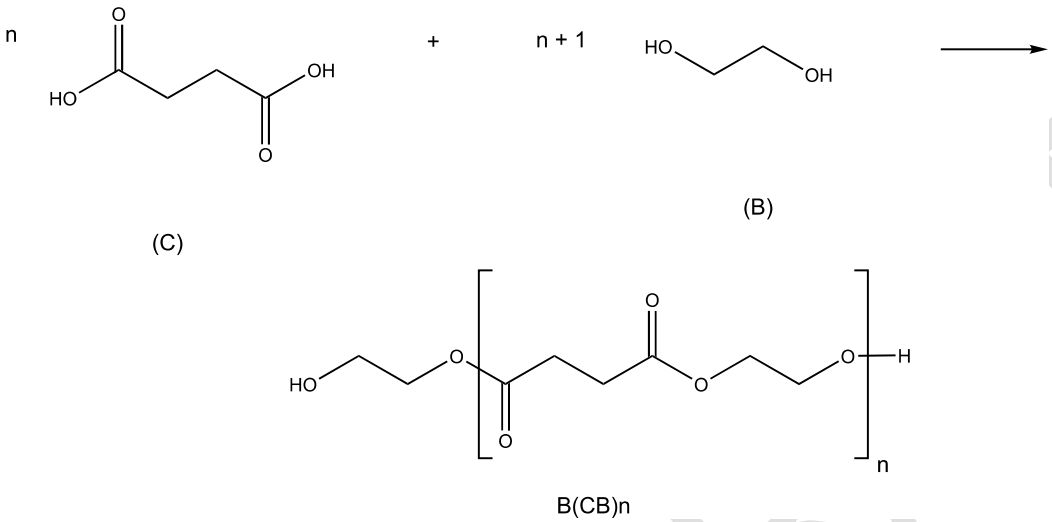


Polymer 1

The final product, Polymer 1, has the structure CB(AB)nC, where component C is derived from a diacid monomer. Because it does not contain reactive groups of concern, it may be considered RRR.

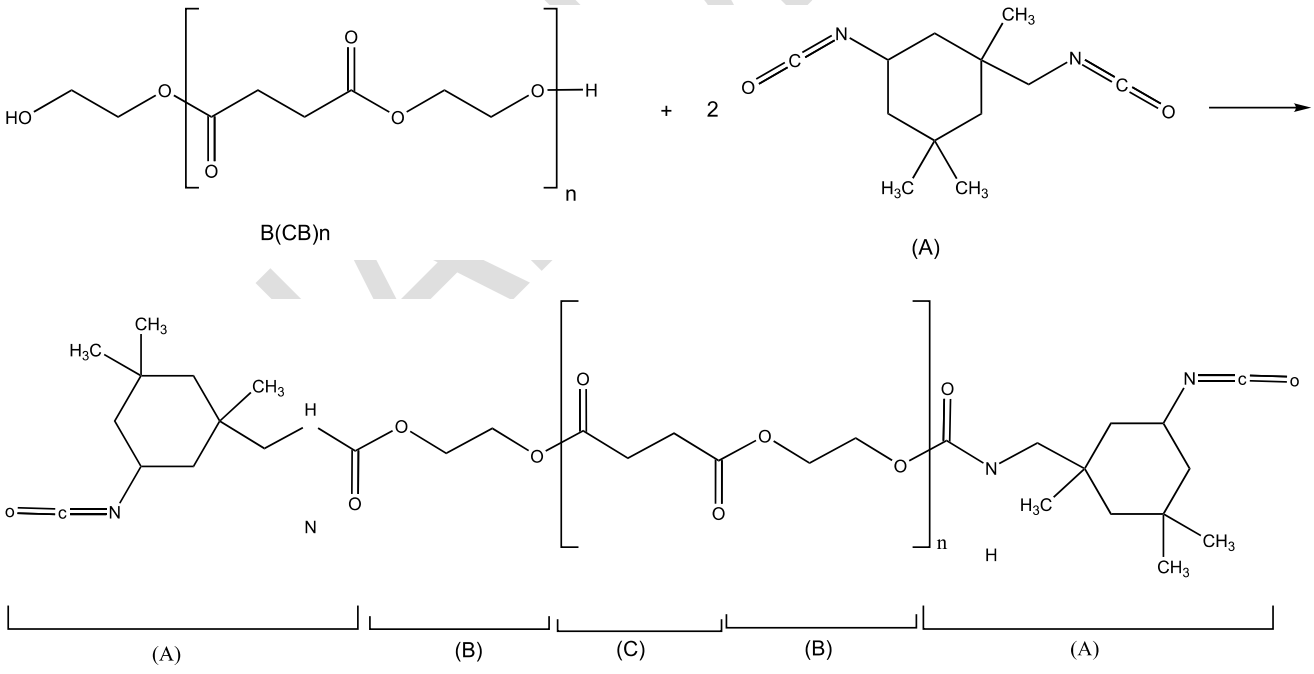
Example 2 – The reaction scheme to obtain Polymer 2 from the same three monomers is as follows.

STEP 1 – Esterification



B(CB)n

STEP 2 –Urethane formation



Polymer 2

Polymer 2 has the structure AB(CB)nA and contains unreacted isocyanates, which are reactive groups of concern. Therefore, this polymer may not be considered RRR.

A8.2 Reaction Scheme Format

The reaction scheme includes both monomer and reactant information and a sequence description.

A8.2.1 Monomer and Reactant Information

The notifier must provide a table of the chemical identities of all monomers, pre-polymers, and reactants along with their Chemical Abstracts Service Registry Number (CAS registry number), molecular weight, percent by weight, and relative number of moles. Each monomer, pre-polymer, and reactant should be assigned an identifier for use in the sequence description.

Identifiers	Monomers and Reactants	CAS registry number	Molecular weight	% by weight	Relative no. of moles
A	Cyclohexane, 5-isocyanato-1-(isocyanatomethyl)-1,3,3- trimethyl-	4098-71-9	222	2.52	11
B	Poly(oxy-1,2-ethanediyl), α- hydro-ω-hydroxy-	25322-68-3	7850	97.22	12
C	Hexane, 1-isocyanato-	2525-62-4	127	0.26	2

A8.2.2 Sequence Description

EITHER

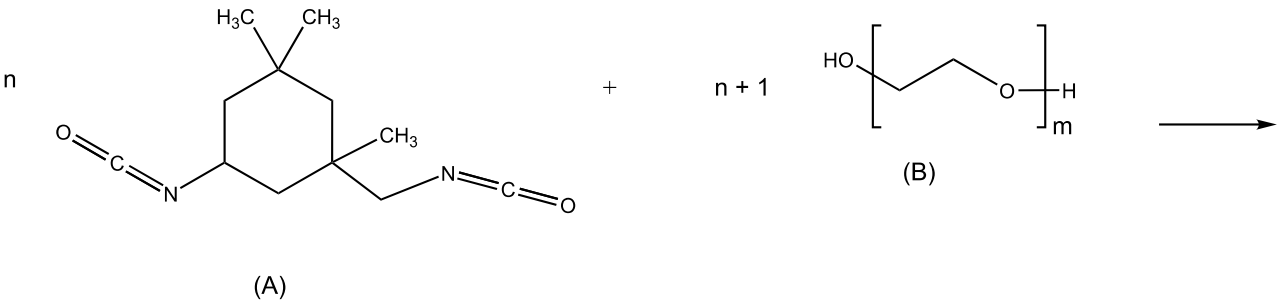
a) Provide the order and description of each step, including the nature of the reactions and the identifiers for all monomers, reactants, and intermediates. For example:

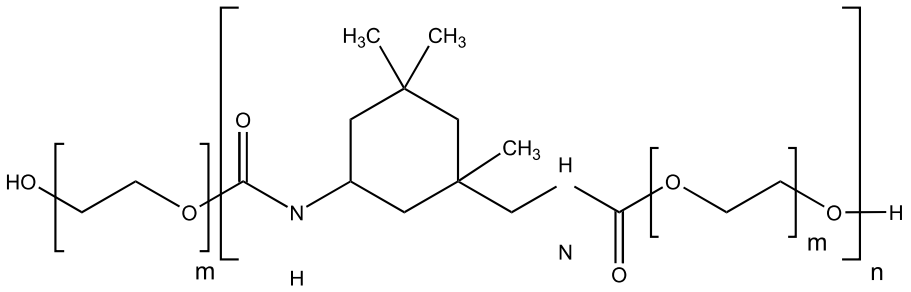
Step 1: A + B → Intermediate AB (*Polyurethane formation*)
Step 2: Intermediate AB + C → Final Product (*Urethane end-cap formation*)

AND/OR

b) Provide a sequencing description that uses structural formulae and includes the order and nature of the reactions and the identifiers for all monomers, reactants, and intermediates. For example:

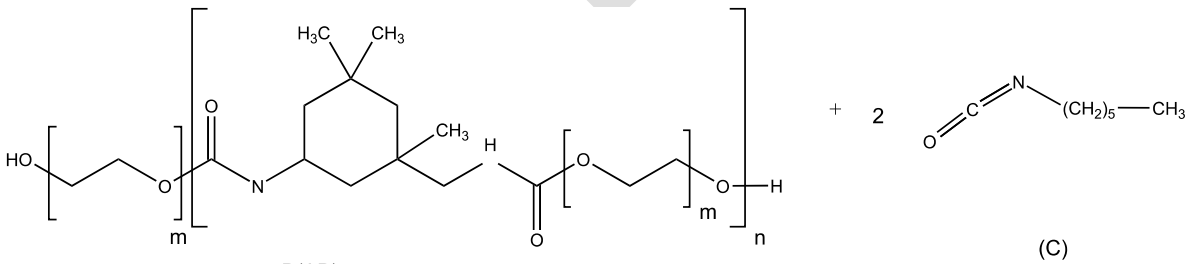
STEP 1 – Polyurethane formation

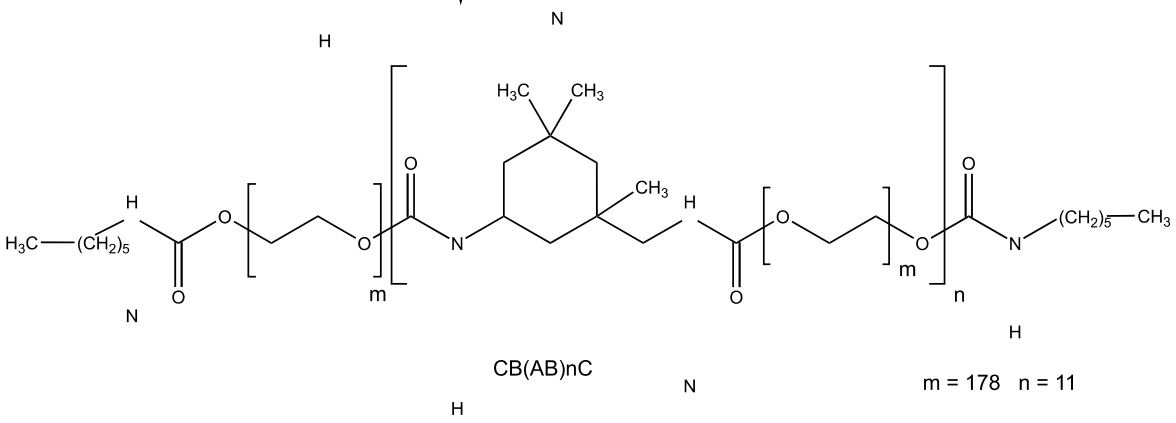




B(AB)n

STEP 2 – Urethane end-cap formation





CB(AB)nC

m = 178 n = 11

Appendix 9 - Guidance on Testing Water Extractability following the Organisation for Economic Co-operation and Development Test Guideline 120

The water availability of polymers notified under Schedule 10 and Schedule 11 of the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) is determined through the information requirement for water extractability. To fulfill this information requirement, the New Substances (NS) program recommends following the experimental protocol for determining water extractability outlined in the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 120: *Solution/Extraction Behaviour of Polymers in Water*.

Polymers are composed of a variety of molecules of differing molecular weights. By virtue of their molecular weight distribution, polymers often form heterogeneous mixtures in water (as opposed to discrete chemicals that can form true thermodynamic solutions). The smaller molecular components of a polymer may dissolve completely, whereas the larger components may form emulsions, dispersions or gels. The water-available fraction of a polymer represents those components that are of greatest interest to human and ecological risk assessments due to their bioavailability.

A9.1 Organisation for Economic Co-operation and Development Test Guideline 120

The OECD TG 120 is an internationally accepted method that can be applied to determine the water extractability of most polymers. The method takes into account that polymers consist of components of different molecular weights and that each component exhibits its own solubility characteristics (i.e. the fraction that can be extracted into the aqueous medium). The following guidance addresses technical issues related to testing polymers for water extractability using OECD TG 120.

A9.2 Technical Guidance for Applying the Organisation for Economic Co-operation and Development Test Guideline 120

A9.2.1Factors Affecting Water Extractability

The water extractability of polymers can be significantly influenced by the test procedures and sample preparation methods. As far as possible, care should be taken to avoid inappropriate test procedures. The NS program may not find studies acceptable where procedures or conditions resulted in interference that affected the study outcomes. Key factors that affect water extractability include the following:

- **Sample preparation**: Methods to separate the polymer from a mixture or isolate it from a solvent must maintain the integrity of the polymeric substance with respect to its molecular weight distribution as well as its water extractability.
- **Surface area of the sample**: Because dissolution predominantly occurs at the surface of the polymer bulk, samples with high surface area (i.e., composed of small particles) dissolve faster.

- **Water volume-to-sample mass ratio**: Using an insufficient amount of water may cause underestimation of extractability results.
- **Rate of mixing**: Stirring replenishes the solvent near the surface of the solute.
- **Temperature**: Heating the solution imparts a higher kinetic energy to dissolve molecules. Heat may also be generated during water/solute interactions (e.g., hydrogen bonding), which in turn, can facilitate dissolution.
- **Water quality**: Some polymers that are not readily available in water may dissolve in aqueous salt solutions ("salting-in" effect). In other cases, salts may reduce the hydration of polymer molecules ("salting-out" effect).
- **pH**: Polymers with ionizable moieties, such as carboxylic acid groups or amine groups, can be rendered more water-available in aqueous solutions by the addition of a base or acid, respectively.
- **Work-up**: The use of high-speed centrifugation or very fine filters may separate extracted material from otherwise stable water dispersion.

A9.2.2Technical Guidance

It is recommended that OECD TG 120 be used for investigating the water extractability of all polymer types, despite the method indicating that it is not applicable to liquid polymers, those that appear as liquids due to impurities like solvents, or substances that react with water under the test conditions. The NS program therefore recommends that the water extractability of polymers be determined using OECD TG 120 with the following guidance:

- The water used should be distilled or deionized.
- As prescribed under the Regulations, the pH of the aqueous phase should be 2, 7 or 9 respectively, prior to adding the notified polymer. The pH should be adjusted with hydrochloric acid or sodium/potassium hydroxide to avoid the use or formation of a buffer system.
- For polymers that are viscous, it is recommended that:
    - solvents not be used to dissolve the polymer;
    - the polymer not be cured or reacted before conducting the test; and
    - the test vessels be prepared by first spreading the substance on the walls of the vessel. This will maximize the surface area of polymer that is exposed to the water and that may become extractable.
- The sample should be agitated for 24 hours at 20°C. Standard laboratory shakers are deemed sufficient to mimic the environmental action of water.
- Although some liquid polymers may not be amenable to testing, the formation of stable liquid dispersions (i.e., emulsions) should be investigated. Stable emulsions are considered by the NS program to be water-available.
- Polymers in solvents should be dried appropriately so that the integrity of the polymer is not affected. For example, heating in an oven to remove residual solvent can result in the loss of oligomers and promote additional polymerization of the substance. Such pre-treatment would be considered by the NS program to invalidate the water extractability results. It is not necessary to attempt to remove all the residual solvent; instead, any remaining solvent can be analyzed along with the polymer sample and that amount can be excluded from the water extractability results.

- Although OECD TG 120 suggests filtration or centrifugation to achieve a clear aqueous phase, the NS program is seeking to quantify the entire bioavailable portion of the polymer, which in certain cases could include a stable dispersion or emulsion in water. Therefore, one of the following techniques may be considered when removing suspended material (see section A9.2.4):
    - Low-speed centrifugation: Considered ideal if conducted over a reasonable time frame (typically for two hours or less) using speeds below ultra-centrifugation.
    - Filtration: Use a filter that does not plug or require excessive pressure (filter sizes that are too small may result in separation of larger-molecular-weight fractions and/or polymer degradation by shear forces in the filter). If clogging occurs, the resulting filtrate will not be representative of the polymer's water availability. Clogging significantly reduces filter pore size, thus invalidating the water extractability result. If the filters clog, centrifugation should be used.

A9.2.3Analysis

OECD TG 120 refers only to a suitable method of analysis for determining the extractable components and suggests different methods for performing this analysis. The NS program recommends aqueous Gel Permeation Chromatography (GPC) as the analytical method, as it allows correlation between molecular weight and water availability, thereby allowing differentiation between extractability of unreacted monomers and additives or impurities.

A9.2.4Reporting

The test report should contain all information required to theoretically be able to repeat the test, including the following:

- All information available on the test sample (identity, additives, impurities, molecular weight information).
- Detailed descriptions of sample preparation, experimental conditions of test performance and analysis, including verification of the applicability of the analytical methodology used (if required).
- The test result must be reported as a percentage of the nominal concentration (loading rate) of the substance. Any calculations needed to obtain this result must be reported in detail.
- All other calculations and any additional information or observations important for the interpretation of the result must be provided.

A9.3 Other Considerations

A9.3.1Completely Water-Available Polymers

Polymers marketed in the form of emulsions or dispersions and those that are capable of forming stable emulsions or dispersions are regarded as "100% water-available."

Therefore, providing water extractability information is not necessary. However, it must be clearly indicated in the New Substances Notification Form that the polymer is 100% water-available. Ecotoxicity, biodegradation and hydrolysis test information continue to be required, as set out in the Regulations.

A9.3.2Surface-Active and/or Water-Dispersed Polymers

In some cases, surface-active polymers can form colloidal dispersions (solid polymers) or emulsions (liquid polymers).

It is not necessary to provide water extractability data for surface-active polymers and polymers formulated in water and marketed as such, since they will be assumed to be completely water-available. Reporting requirements for this type of polymer are addressed in section 10.3.1 of this Appendix**.**

A9.3.3Waivers for Water Extractability

If a polymer is considered completely water-available, a statement to that effect is sufficient to address the water extractability requirement. A waiver request is not required.

If surrogate or alternate data are provided, a waiver request is not necessary.

If a waiver for water extractability is granted and the percent extractability of the notified polymer remains unknown, ecotoxicity, biodegradation and hydrolysis test information continue to be required, as set out in the Regulations.

A9.3.4Testing of Water-Reactive Polymers

Polymers containing water-reactive functional groups, such as isocyanates and alkoxysilanes, may be of concern. Consequently, if the presence of these reactive functional groups exceeds the thresholds set out in Schedule 7 of the Regulations, the polymer would not be considered a Reduced Regulatory Requirement polymer (see section 3.3.1.5). Information about a polymer's behaviour in water is needed in order to conduct an assessment, and notifiers are required to provide water extractability information under Schedule 10 or Schedule 11 of the Regulations.

It is generally recognized that polymers with water-reactive functional groups, such as isocyanates and alkoxysilanes, undergo hydrolysis. Hydrolysis may be followed by a self-condensation reaction that can lead to an increased molecular weight and the reduced solubility of the polymer. However, the rates of hydrolysis, the potential for self-condensation and the solubility of the resulting substance is dependent on the structural characteristics of the individual polymer.

It is also recognized that the hydrolysis and possible self-condensation reactions may reduce the practicability of conducting water-based testing (e.g., ecotoxicity). For these reasons, the Regulations were structured to include an exemption from certain testing

requirements (e.g., hydrolysis, biodegradation, ecotoxicity) for polymers with limited water extractability.

In order to be eligible for exemptions from certain testing requirements, the Regulations require water extractability information. The NS program recommends that a water extractability test be conducted according to OECD TG 120. While there can be challenges with conducting water extractability testing on water-reactive polymers, the OECD TG 120 test method is considered to be the most relevant method in order to generate information meaningful for the assessment of water-reactive polymers.

Water extractability information will provide direct evidence on the solubility of a polymer and will determine whether or not further testing is required:

- If the water extractability is > 2%, the polymer is subject to ecotoxicity, biodegradation and hydrolysis testing, as set out in the Regulations.
- If the water extractability is ≤ 2%, the notified polymer is not subject to ecotoxicity, biodegradation and hydrolysis testing, as set out in the Regulations.

Overall, the testing strategy for water-reactive polymers is best addressed by performing the water extractability test on the notified polymer. Water extractability may also be obtained from alternative approaches (see section 8.4) or waivers (see section 8.7). Where waivers are requested, a stand-alone claim that a polymer is highly reactive with moisture converting it into a very high molecular weight cross-linked polymer is not sufficient, given that hydrolysis and self-condensation rates are dependent on the structural characteristics of the individual polymer. A waiver request needs to be accompanied by a well-documented scientific rationale, which includes supporting information (e.g., empirical or read-across data) to demonstrate the water-reactivity and condensation behaviour.

If unsure, notifiers should consult with the NS program through a Pre-notification Consultation request (see section 8.8) in order to determine the most appropriate testing strategy for water-reactive polymers.

Appendix 10 - Assessment of Nanomaterials under the New Substances program

Nanomaterials typically have larger surface area-to-volume ratios relative to their non-nanoscale forms, which can lead to greater reactivity. They may also exhibit differences in other chemical and physical properties that cannot be predictably extrapolated from their non-nanoscale forms. These differences may affect the potential of a substance to pose a risk to human health or the environment.

In line with the 2013 Organisation for Economic Co-operation and Development (OECD) Council Recommendation,[35] Canada is using its existing chemical regulatory framework to manage nanomaterials, making adaptations where necessary to take into account the specific properties of nanomaterials.

While there is no internationally aligned regulatory definition, the New Substances (NS) program is using the Health Canada Working Definition of Nanomaterial: "(1) having one or more dimensions (or internal or surface structure) at the nanoscale (1–100 nanometers inclusive); or (2) exhibiting nanoscale-related properties and/or phenomena above or below the nanoscale."

The NS program may request information about primary particle size and particle size distribution in order to determine whether a notified substance is at the nanoscale. Various methods, based on different physical principles, are available to measure primary particle size and particle size distribution:

- OECD. 2016. Physical-chemical properties of nanomaterials: evaluation of methods applied in the OECD-WPMN testing programme. ENV/JM/MONO(2016)7. Available on-line at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2016)7&doclanguage=en

If information about primary particle size and particle size distribution is not provided, and the NS program believes that the substance could be a nanomaterial, the substance will be treated as a potential nanomaterial. Providing this information will allow for better identification of new nanomaterials, leading to more informed risk assessment and if necessary, more appropriate control measures. While the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) prescribe the information that must be submitted to the NS program, they also generally require the submission of all other information and test data in the possession of the manufacturer or importer or to which they may reasonably be expected to have access.

[35] Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials. Available online at: https://legalinstruments.oecd.org/en/instruments/298.

The NS program may recommend submitting certain other information to take into account the specific properties of nanomaterials. The information could include, but is not limited to:

- physico-chemical properties specific to each nanomaterial, including agglomeration (aggregation) state, shape, surface area, surface functionalization, surface coating and surface charge, etc. of the substance;
- release potential of the substance from a final product;
- ecotoxicity data and test report (e.g, soil toxicity); and
- mammalian toxicity test by inhalation route of exposure (including acute toxicity and repeated-dose toxicity) conducted according to revised OECD Test Guidelines (TGs). Revised Guidance Document on Inhalation Toxicity Testing and updated inhalation toxicity studies (TGs 412 and 413) addressing nanospecific issues are available online.[36, 37, 38]

Although not required, notifiers are encouraged to submit a Pre-notification Consultation (PNC) request (see section 8.8), while the New Substances Notification (NSN) is being prepared, in order to seek advice on nanomaterial-specific considerations, such as additional data that could support the risk assessment, and guidance on test methods.

[36] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)28/rev1&doclanguage=en
[37] https://www.oecd-ilibrary.org/environment/test-no-412-subacute-inhalation-toxicity-28-day-study_9789264070783-en
[38] https://www.oecd-ilibrary.org/environment/test-no-413-subchronic-inhalation-toxicity-90-day-study_9789264070806-en

Appendix 11 - International Arrangements

International arrangements are ongoing and changing. To ensure current information, visit our website:

https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/chemicals-polymers/international-cooperation.html

Appendix 12 - Parts of the Domestic Substances List and the Non-domestic Substances List

Domestic Substances List

The Domestic Substances List (DSL) (SOR/94-311) provides an inventory of substances in the Canadian marketplace. It was originally published in the *Canada Gazette*, Part II, in May 1994. The current structure of the DSL was established in 2001 (*Order 2001-87-04-01 Amending the Domestic Substances List* (SOR/2001-214)) and amended in 2012 (*Order 2012-87-09-01 Amending the Domestic Substances List* (SOR/2012-229)). The DSL is amended, on average, 10 times per year to add, update or delete substances.

The DSL includes eight parts defined as follows:

Table A12-1 Parts of the Domestic Substances List

Part	Description
1	Sets out chemicals and polymers, except those referred to in Part 2, 3 or 4, that are identified by their Chemical Abstracts Service Registry Number (CAS registry number), or their Substance Identity Number assigned by the Department of the Environment and the name of the substance.
2	Sets out chemicals and polymers subject to Significant New Activity (SNAc) requirements that are identified by their CAS registry number.
3	Sets out chemicals and polymers, except those referred to in Part 4, that are identified by their masked name and their Confidential Substance Identity Number (also referred as Confidential Accession Number (CAN)) assigned by the Department of the Environment.
4	Sets out chemicals and polymers subject to SNAc requirements that are identified by their masked name and their Confidential Substance Identity Number.
5	Sets out inanimate biotechnology products and living organisms, except those referred to in Part 6, 7 or 8, that are identified by their American Type Culture Collection (ATCC) number, International Union of Biochemistry and Molecular Biology (IUBMB) number or specific substance name.
6	Sets out inanimate biotechnology products and living organisms subject to SNAc requirements that are identified by their ATCC number, IUBMB number or specific substance name.
7	Sets out inanimate biotechnology products and living organisms, except those referred to in Part 8, that are identified by their masked name and their Confidential Substance Identity Number.
8	Sets out inanimate biotechnology products and living organisms subject to SNAc requirements that are identified by their masked name and their Confidential Substance Identity Number.

Non-domestic Substances List

The Non-domestic Substances List (NDSL) provides an inventory of substances found in international commerce. It was originally published in the *Canada Gazette*, Part I, in January 1998 (volume 132, no.5). The NDSL is amended, on average, two times per year to add, update or delete substances.

The NDSL includes four parts defined as follows:

Table A12-2 Parts of the Non-domestic Substances List

Part	Description
1	Sets out chemicals and polymers, except those referred to in Part 2, that are identified by their CAS registry number.
2	Sets out chemicals and polymers that are identified by their masked name in accordance with the *Masked Name Regulations*, and by their Confidential Substance Identity Number assigned by the Department of the Environment.
3	Sets out enzymes, except those referred to in Part 4, identified by their IUBMB number.
4	Sets out enzymes identified by their masked name in accordance with the *Masked Name Regulations*, and by their Confidential Substance Identity Number assigned by the Department of the Environment.

Appendix 13 - Glossary, Abbreviations and Acronyms and Hyperlinks

A13.1 Glossary

Acceptable to the New Substances (NS) program with respect to a test method means a method that enables a sufficient quantity and quality of data to be generated for a meaningful assessment of the endpoint under investigation by the NS program. Important considerations of the method include the use of standards and controls; detection limits; species selected; tissues investigated; doses; adherence to Good Laboratory Practices; validation of the method; and statistical power of the method (see also **indicator of mutagenicity**).

Act means the *Canadian Environmental Protection Act, 1999*.

Adequately contained means all precautions and measures necessary to prevent the release of the substance to the environment. With respect to the transportation of a substance, adequate containment requires full compliance with the *Transportation of Dangerous Goods Act* (see also **contained**).

Amphoteric polymer/biopolymer means a polymer that has monomer units that are covalently bound and bear both a negative charge and a positive charge (see also **monomer unit, polymer**).

Animal includes a part of an animal, but does not include an animal or part of an animal that exists primarily as a single cell and is without the organization that characterizes tissues or organs.

Anionic polymer/biopolymer means a polymer that has one or more monomer units that are covalently bound and bear a net negative charge (see also **monomer unit**, **polymer**).

Assessment period means the number of calendar days that the government has to assess the information submitted by a notifier under the Regulations.

Biochemical means a chemical that is produced by a micro-organism, or means a protein or a nucleic acid derived from a plant or an animal. Note: dead micro-organisms are considered biochemicals.

Biopolymer means a polymer that is produced by a micro-organism, or means a protein or a nucleic acid derived from a plant or an animal.

Biotechnology means the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.

By-product means a substance produced without separate commercial intent during the manufacture of another substance.

Canadian Agent means the agent required when a notifier who provides the information under the Regulations is not a resident in Canada. The notifier must identify, under paragraph 14(1)(*b*) of the Regulations, a person resident in Canada as a "Canadian Agent" authorized to act on their behalf. The "Canadian Agent" is required to receive any notice or correspondence that may be sent in relation to the New Substances Notfication (NSN) and keep a copy of the NSN and all correspondence and supporting data with respect to the NSN, for the period of five years after the end of the year in which the information is provided (see section 13 of the Regulations). **The "Canadian Agent" is responsible for ensuring that information in the NSN is accurate and complete.**

Chemical Abstracts Service Registry Number means the identification number assigned to a substance by the Chemical Abstracts Service Division of the American Chemical Society.

Cationic polymer/biopolymer means a polymer that has one or more monomer units that are covalently bound and bear a net positive charge (see also **monomer unit**, **polymer**).

Chemical means a substance that is not a polymer.

Consumed, in respect of a substance, means destroyed or completely converted to another substance.

Contained, in respect of a site-limited intermediate substance or an export-only substance, means an absolute release limit of 1 kg per day per site to the aquatic environment after wastewater treatment.

Direct public exposure to a substance results from direct contact with, or close proximity to, the substance during any part of its life cycle (manufacture, processing and handling, storage, transportation, use, disposal) whether knowingly or not. Direct exposure to the substance occurs by the same environmental media into which the substance was released. With respect to the Regulations, this refers to exposure of the general population in Canada. This differs from indirect public exposure, which involves exposure to the substance in a medium different from that into which the substance was released.

Domestic Substances List means the list maintained by the Minister under subsection 66(1) of the Act, as amended from time to time by the Minister under subsection 66(3) or subsections 87(1), (3), and (5) of the Act (see also **Non-domestic Substances List**).

Evidence that the tissue investigated was exposed to the substance or its metabolites with respect to the *in vivo* mutagenicity test in Schedule 6 and Schedule 11 of the Regulations is necessary to determine the appropriateness of the tissue(s) investigated in assessing the *in vivo* mutagenicity of a substance, and thus the adequacy of the test. This clause indicates the need for sufficient information to support a conclusion that the tissue investigated was exposed to the test substance or its metabolites. The strength of the evidence required will be balanced with the concern of the mutagenic potential of the substance, for example: results from *in vitro* mutagenicity tests; structure; potential for exposure; tissue investigated; and test method. Examples of what may constitute evidence of tissue exposure include the following:

a) a positive result for the test endpoint in the tissue investigated;

b) cytotoxicity observed in the tissue investigated, e.g., statistically significant reduction in the mitotic index, cell cycle delay, decrease in the ratio of polychromatic to normochromatic erythrocytes;

c) general organ toxicity in the tissue investigated, e.g., significant change in organ weight or hyperplasia; and

d) data from a tissue distribution study indicating the presence of the substance or its metabolites in the tissue investigated.

Importer or Importer of Record means the person importing the substance as shown on the Canadian Customs coding Form (Form B3-3) as issued by the Canada Border Services Agency.

Impurity means a substance whose presence with another substance is not intentional, is not necessary to the end-use of the product, and does not enhance the commercial value of the product.

Indicator of mutagenicity with respect to permitting an assessment of *in vitro* or *in vivo* mutagenicity means tests that are “acceptable to the New Substances program” for determining the *in vitro* or *in vivo* mutagenic potential of the substance. This wording is intended to permit the selection of the most appropriate test(s) for a substance, and to allow developments in the field of genotoxicity to quickly become part of a testing strategy. It is recommended that the investigator consult with Health Canada officials before testing to determine the acceptability of a test for that specific substance (see also **Acceptable to the New Substances program**).

In the possession of the manufacturer or importer means the information in the company’s offices in Canada if the New Substances Notification (NSN) was submitted by a Canadian company or the information in the offices in the country where the notification orginated if the NSN was submitted by a foreign company through a “Canadian Agent” (see also **to which they may reasonably be expected to have access**).

Living organism means a substance that is an animate product of biotechnology, and refers to micro-organisms or organisms other than micro-organisms.

Masked name means a name based on the Chemical Abstracts Service (CAS), the International Union of Pure and Applied Chemistry (IUPAC) or the International Union of Biochemistry and Molecular Biology (IUBMB) nomenclature, but having one or more of the specific components identified in a manner that prevents the identification of the specific chemical structure. Masking a substance name will only be acceptable to the extent necessary to disguise the full identity of the substance, while retaining the generic molecular structure. Substances published with a masked name are assigned a Confidential Substance Identity Number (also referred to as a Confidential Accession Number by the program).

Micro-organism means a microscopic organism that is

a) classified in the Bacteria, the Archaea, the Protista, which includes protozoa and algae, or the Fungi, which includes yeasts;

b) a virus, virus-like particle or sub viral particle;

c) a cultured cell or an organism not referred to in paragraph a) or b), other than a cell used to propagate the organisms; or

d) any culture other than a pure culture.

Minister means the Minister of the Environment; whereas, Ministers means the Minister of the Environment and the Minister of Health.

Monomer unit means the reacted form of a monomer in a polymer (see also **polymer**).

Most significant route of potential public exposure means exposure of the general population in Canada. To select the most appropriate route or routes for testing, the expected concentration of the notified substance in the various environmental media and consumer products and the bioavailability of the substance through ingestion, inhalation and dermal absorption must be considered. The most significant route of exposure to a substance for the general population may be different from exposures for workers in an occupational setting. Consequently, data generated for occupational exposures may not meet the requirement for the most significant route of potential public exposure specified in the Regulations.

New substances mean substances that are not presently on the Domestic Substances List and are considered to be new to Canada. Regulations were created to ensure that no new substances (chemicals, polymers or animate products of biotechnology) are introduced into the Canadian marketplace before an assessment of whether they are

potentially toxic has been completed, and any appropriate or required control measures have been taken.

Non-domestic Substances List means the list maintained by the Minister under subsection 66(2) of the Act, as amended from time to time by the Minister under subsection 66(3) or subsections 87(1) and (5) of the Act (see also **Domestic Substances List**).

Person includes legal and natural persons such as corporations or individual residents of Canada.

Plant includes a part of a plant, but does not include a plant or part of a plant that exists primarily as a single cell and is without the organization that characterizes tissues or organs.

Polymer means a substance that consists of

a) molecules characterized by the sequence of one or more types of monomer units;

b) greater than 50% by weight of molecules having three of more monomer units that are covalently bound to one or more other monomer units or reactants;

c) less than 50% by weight of molecules of the same molecular weight; and

d) molecules distributed over a range of molecular weights whose differences in molecular weights are primarily attributable to differences in the number of monomer units (see also **monomer unit**, **reactant**).

Product development substance means a research and development substance that is evaluated in one program of two years or less in length before full commercialization by means of pilot plant trials, production trials, or customer trials to modify technical specifications in response to performance requirements of potential customers but does not include test marketing (see also **research and development substance**, **test marketing**).

Reactant, in respect of a polymer, means a substance that is used in the manufacture of the polymer and becomes part of its chemical composition, and includes a monomer.

Reactive functional group means atoms or an associated group of atoms in a substance that are intended or may reasonably be expected to undergo facile chemical reaction.

Read-across estimate means a qualitative estimate of a property of a substance based upon experimental data from (an) other compound(s) having a closely related chemical structure.

Reduced regulatory requirement polymer means one of the polymers described in section 9 of the Regulations.

Regulations means the *New Substances Notification Regulations (Chemicals and Polymers)* of the *Canadian Environmental Protection Act, 1999*.

Research and development substance means a substance that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing, whose primary objective is any of the following:

a) to create or improve a product or process;

b) to determine the technical viability or performance characteristics of a product or process; or

c) to evaluate the substance prior to its commercialization, by pilot plant trials, production trials, including scale-up, or customer plant trials, so that technical specifications can be modified in response to the performance requirements of potential customers (see also **test marketing**).

Safety Data Sheet, in respect of a substance, has the same meaning as in section 2 of the *Hazardous Products Act*.

Site-limited intermediate substance means a substance that is consumed in a chemical reaction used for the manufacture of another substance and that is

a) manufactured and consumed at the site of manufacture;

b) manufactured at one site and transported to a second site where it is consumed; or

c) imported and transported directly to the site where it is consumed.

Substance. A substance is defined in subsection 3(1) and section 80 of the Act as

"*any distinguishable kind of organic and inorganic matter, whether animate or inanimate, and includes*

(a) any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformations in the environment;

(b) any element or free radical;

(c) any combination of elements of a particular molecular identity that originate in nature or are the result of chemical reactions but could not practicably be formed by simply combining individual constituents; and

(d) complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not practicably be formed by simply combining individual constituents."

for the purposes of the new substances provisions of the Act (e.g., section 66 and sections 80 to 89 concerning chemicals and polymers), does not include:

"*(e) any mixture that is a combination of substances and does not itself produce a substance that is different from the substances that were combined;*

(f) any manufactured item formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design; and,

(g) any animate matter that is, or any complex mixture of different molecules that are, contained in effluents, emissions or wastes that result from any work, undertaking or activity."

Substance occurring in nature means a substance that is naturally occurring, and is unprocessed; processed only by manual, gravitational or mechanical means, by dissolution in water, by flotation, or by heating solely to remove water; or extracted from air by any means.

Third Party Information Supplier is a term used when the notifier is not given access to information that is considered confidential by the third party. The information to support the New Substances Notification must be supplied directly to the New Substances program by the third party and will be identified as a "Third Party Information Supplier Submission." Third Party Information Supplier include foreign suppliers; a Third Party Information Supplier can be located in Canada or elsewhere.

Test marketing, in respect of a product, means the exploration of its market capability in a competitive situation where the creation or improvement of the product is not the primary objective (see also **research and development substance**).

Toll Manufacturer means the person who is actually producing the substance, whether the activity is done on toll or otherwise for the benefit of another person.

Transient reaction intermediate means a substance that is formed and consumed in the course of a chemical reaction.

To which they may reasonably be expected to have access means information in any of the company's offices worldwide, or other locations where the person can access the information (see also **in the possession of the manufacturer or importer**).

Trigger quantity means the quantity of substance manufactured or imported that, if exceeded, requires the notifier to provide a New Substances Notification. For example, for a chemical/biochemical listed on the Non-domestic Substances List, the trigger quantity requiring a Schedule 4 notification is 1 000 kg/yr.

UVCB is an abbreviation for **U**nknown or **V**ariable composition **C**omplex reaction products or **B**iological material. These materials are derived from natural sources or complex reactions and are considered to be a single substance for notification purposes.

A13.2 List of Abbreviations and Acronyms

AICIS	Australian Industrial Chemicals Introduction Scheme
AICS	Australian Inventory of Chemical Substances
amine	cationic amine
ASTM	American Society for Testing and Materials
BA	branching agent
BP	branched polymer
CA	Chemical Abstracts
CAS	Chemical Abstracts Service
CAS registry number	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
comb	combined
CPI	Consumer Price Index
CTFA	Cosmetic, Toiletry and Fragrance Association
DRave mo	daily release to the aquatic environment averaged monthly
DSL	Domestic Substances List
EC50	median effective concentration
ECHA	European Chemicals Agency
ECL	Korean Existing Chemicals List
ECOIN	European Core Inventory
EINECS	European Inventory of Existing Commercial Substances
F&DA	Food and Drugs Act
FGEG	functional group in end group position
FGEW	functional group equivalent weight
FGEWn	individual functional group equivalent weight calculation (n = 1, 2, 3, …)
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GLP	Good Laboratory Practice
GPC	Gel Permeation Chromatography
INN	International non-proprietary names
IR	Infrared
ISA	Information-Sharing Agreement
ISO	International Organization for Standardization
IUBMB	International Union of Biochemistry and Molecular Biology
IUPAC	International Union of Pure and Applied Chemistry
LC50	median lethal concentration
LD50	median lethal dose
LOEC	lowest-observed-effect-concentration
LP	linear polymer
MALLS	Multi Angle Laser Light Scattering

MALS	Multi Angle Light Scattering
Mn	number average molecular weight
mon	monomer
MP	molecular weight of the highest peak
mw	molecular weight
Mw	weight average molecular weight
mw KOH	molecular weight of KOH = 56.1 g/mol
Mz	z average molecular weight
NAICS	North American Industry Classification System Code
NDSL	Non-domestic Substances List
nEG	number of end groups
nFG	number of available functional groups
NMR	Nuclear Magnetic Resonance
NOEC	no-observed-effect concentration
NOEQ	Notice of Excess Quantity
NOMI	Notice of Manufacture or Import
non-RRR	Non-reduced Regulatory Requirement polymers
nRS	number of reactive sites
NS program	New Substances program
NSFR	New Substances Fees Regulations
NSN	New Substances Notification
OECD	Organisation for Economic Co-operation and Development
PMN	Pre-Manufacture Notice
PNC	Pre-notification Consultation
QMRF	QSAR Model Reporting Format
QPRF	QSAR Prediction Reporting Format
QR	quantity released
QSAR	Quantitative Structure-Activity Relationship
RDM	number of release days per month
RE	removal efficiency
RRR	Reduced Regulatory Requirement polymers
RTECS	Registry of Toxic Effects of Chemical Substances
SDS	Safety Data Sheet
SEC	Size-exclusion Chromatography
SNAc	Significant New Activity
SNAN	Significant New Activity Notification
TG	Test Guideline
the Act	Canadian Environmental Protection Act, 1999
the Minister	the Minister of the Environment
the Ministers	the Minister of the Environment and the Minister of Health
the Regulation	New Substances Notification Regulations (Chemicals and Polymers)
TSCA	Toxic Substances Control Act

US EPA	United States Environmental Protection Agency
UV	Ultraviolet
UVCB	Unknown or Variable composition Complex reaction product or Biological material
wt%	weight percent
Xamine	amine number, mg KOH/g polymer

A13.3 List of Hyperlinks

Additional Significant New Activity Guidance
https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/significant-new-activity-provisions.html

Canada Gazette, Part I, in January 1998 (volume 132, no. 5)
http://www.gazette.gc.ca/rp-pr/p1/1998/1998-01-31/pdf/g1-13205.pdf

Canadian Environmental Protection Act, 1999 Compliance and Enforcement Policy
https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/compliance-enforcement-policy.html

Canadian Environmental Protection Act, 1999 Registry
https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry.html

Canadian Federal Business Number
https://www.canada.ca/en/services/taxes/business-number.html

Chemical Abstracts Service
https://www.cas.org/

Domestic substances List
https://pollution-waste.canada.ca/substances-search/Substance/SearchByListOrGroup?ListGroupCode=DSL&viewOnline=View+online&lang=en

Environment and Climate Change Canada Biological Test Methods
https://www.canada.ca/en/environment-climate-change/services/wildlife-research-landscape-science/biological-test-method-publications.html

Environment and Climate Change Canada Single Window system
https://ec.ss.ec.gc.ca

Enzyme Commission numbers
https://www.qmul.ac.uk/sbcs/iubmb/enzyme/

Example of United States Environmental Protection Agency Test Methods
https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=91014VJA.txt

Genotoxicity of Manufactured Nanomaterials: Report of the OECD Expert Meeting
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)34&doclanguage=en

Guidance Document on Inhalation Toxicity Testing
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)28/rev1&doclanguage=en

Guidance Document on Transformation/Dissolution of Metals and Metalcompounds in Aqueous Media
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2001)9&doclanguage=en

Guidance for responding to the Notice with respect to certain nanomaterials in Canadian Commerce
https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=AACFB2C0-1

Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2012)40&doclanguage=en

International arrangements
https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/chemicals-polymers/international-cooperation.html

Certification Form – Interpretation of Person
https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notification-forms.html

Nanomaterials Working Definition
https://www.canada.ca/en/health-canada/services/science-research/reports-publications/nanomaterial/policy-statement-health-canada-working-definition.html

New Substances Notification Fees

https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html

New Substances Notification Form
https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notification-forms.html

New Substances program
https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html

New Substances program's search engine
https://pollution-waste.canada.ca/substances-search/Substance?lang=en

Nomination Form – Non-domestic Substances List
https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notification-forms.html

Non-Domestic substances List
https://pollution-waste.canada.ca/substances-search/Substance/SearchByListOrGroup?ListGroupCode=NDSL&viewOnline=View+online

North American Industry Classification System Code (NAICS)
https://www23.statcan.gc.ca/imdb/p3VD.pl?Function=getVD&TVD=307532

OECD (2014). Guidance Document on the Grouping of Chemicals, OECD Environment Health and Safety Publications. Series on Testing and Assessment. No. 194 (ENV/JM/MONO(2014)4)

http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en

OECD Decision of the Council Concerning the Mutual Acceptance of Data in the Assessment of Chemicals, adopted by the OECD on May 12, 1981
https://legalinstruments.oecd.org/en/instruments/263

OECD Guidelines for the Testing of Chemicals

https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_72d77764-en

OECD harmonized template format
http://www.oecd.org/ehs/templates/

OECD guidance documents and TGs specific to nanomaterials
http://www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm

OECD TG 412
https://www.oecd-ilibrary.org/environment/test-no-412-subacute-inhalation-toxicity-28-day-study_9789264070783-en

OECD TG 413
https://www.oecd-ilibrary.org/environment/test-no-413-subchronic-inhalation-toxicity-90-day-study_9789264070806-en

OECD. 2016. Physical-chemical properties of nanomaterials: evaluation of methods applied in the OECD-WPMN testing programme. ENV/JM/MONO(2016)7
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2016)7&doclanguage=en

Order 2001-87-04-01 amending the Domestic Substances List
http://www.gazette.gc.ca/rp-pr/p2/2001/2001-07-04/pdf/g2-13514.pdf

Order 2012-87-09-01 amending the Domestic Substances List
http://gazette.gc.ca/rp-pr/p2/2012/2012-11-21/html/sor-dors229-eng.html

Organisation for Economic Cooperation and Development (OECD). 2013. Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials.
https://legalinstruments.oecd.org/en/instruments/298

Recognized ports of entry
https://www.cbsa-asfc.gc.ca/do-rb/services/menu-eng.html

Recommendation of the Council concerning the OECD List of Non-Confidential Data on Chemicals 26 July 1983 - C(83)98/FINAL
https://legalinstruments.oecd.org/en/instruments/32

Report from the Expert Group on (Quantitative) Structure–Activity Relationships [(Q)SARs] on the Principles for the Validation of (Q)SARs
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?doclanguage=en&cote=env/jm/mono(2004)24

Series of decisions and guidelines relating to GLP
https://www.oecd.org/env/ehs/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

Significant New Activity Publications under the *Canadian Environmental Protection Act, 1999*
https://open.canada.ca/data/en/dataset/bfab5876-77e5-4dbf-8693-3b0bc69428b8

Source of Test Methods OECD
https://www.oecd.org/chemicalsafety/testing/

US EPA. 2017. Chemical substances when manufactured or processed as nanoscale materials: TSCA reporting and recordkeeping requirements
https://www.govinfo.gov/content/pkg/FR-2017-01-12/pdf/2017-00052.pdf